SCIENTIFIC RETREAT 2020

Breaking the Barrier:

Getting Beyond 50% Long-term Survival for Patients with Advanced Melanoma

Highlights from the 2020
Melanoma Research Alliance Scientific Retreat

Melanoma Research Alliance

Contents

Letter from Chief Science Officer and Senior Director, Scientific Program

Marc Hurlbert, PhD

Kristen L. Mueller, PhD

Each year, the Melanoma Research Alliance looks forward to hosting the annual Scientific Retreat. The 2020 Retreat took place from February 26-28 in Washington, DC. The gathering brought together key members of the melanoma community — researchers, clinicians, patients and their loved ones, as well as representatives from industry, government, scientific journals, and other foundations — for three days of scientific presentations, conversations, and learning.

This year's Retreat featured presentations from 20 researchers, including a keynote lecture from Nobel Laureate and MRA Scientific Advisory Panel member Jim Allison. Central to these presentations, and to the Retreat as a whole, was engaging the melanoma community around the question of how to maintain innovation to improve outcomes for patients. Innovation led to the approval of 12 new treatments in the past decade and pushed survival rates to five years or more for nearly 50% of advanced melanoma patients on combination immunotherapy — but how can this promise be realized for the other half of melanoma patients?

Scientific sessions focused on novel therapeutic approaches, understanding melanoma initiation and metastasis, as well as a special session on acral melanoma, among others, highlighted the innovative approaches being taken by MRA-funded researchers that continue to raise the bar for patients who do not respond to the currently approved therapies. Research presented, which was largely unpublished, demonstrated that approaches such as treating patients with systemic therapy at earlier stages of disease, using artificial intelligence (AI) to improve the accuracy of melanoma diagnosis, and designing studies so clinical data can advance laboratory studies and vice versa have the potential to lead to better outcomes for patients in the near future.

Beyond the scientific presentations, the Retreat featured the Melanoma > Exchange Advocates Forum where patients, their family members, and caregivers had the opportunity to gather with experts to learn about the latest advances in treatment, the importance of animal models to propel research forward, and tools for how to separate hope from hype in the media coverage of melanoma and cancer treatment more broadly. The Forum also featured a guest appearance by U.S. Surgeon General Jerome Adams, who highlighted the importance of advancing melanoma prevention and early detection efforts.

The program also included a breakfast for MRA Young Investigator Awardees focused on the importance of mentorship in scientific research, a poster session where MRA-funded researchers had the opportunity to present their work, and two topic-focused networking sessions. MRA also hosted an Industry Roundtable discussion focused on how industry, researchers, clinicians, and regulatory officials can work together to improve survival outcomes for melanoma patients not benefitting from currently approved therapies. MRA's goal is that the conversations and collaborations sparked by these events will continue to accelerate progress in melanoma prevention, detection, diagnosis, and treatment.

The science presented and ensuing discussions help MRA set its priorities in the coming year. We are delighted to share highlights from the 2020 Scientific Retreat with you, which we are sure will lead to critical advances for melanoma patients in the near future.

Sincerely,

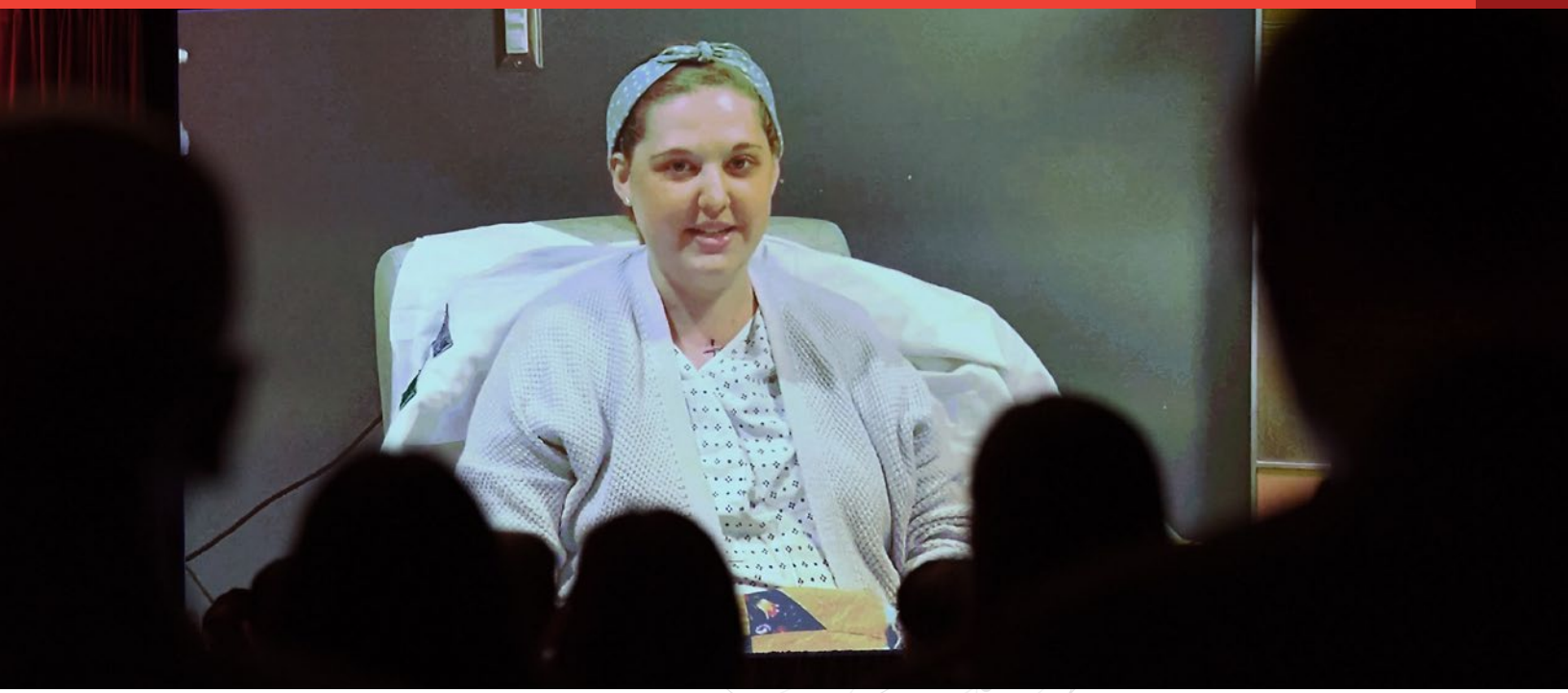
Marc Hurlbert, PhD
Chief Science Officer

Kristen L. Mueller, PhD
Senior Director, Scientific Program

Maintaining Momentum:

Advancing Treatment Approaches, Understanding Patients' Holistic Needs, and Preventing New Melanomas

Maintaining Momentum



Graze Wenzel provides opening remarks from her hospital bed

The last decade has been one of substantial progress and hope for many melanoma patients, researchers, and clinicians. With 12 new therapeutic approaches now approved to treat melanoma, many advanced-stage patients are seeing their tumors shrink or disappear, and are experiencing renewed hope for a brighter future. Given this exceptional progress, researchers, clinicians, patients and their caregivers, as well as representatives from industry, biotech, non-profits, and government gathered at the 2020 MRA Scientific Retreat to hear updates on the latest research, to discuss how to keep this incredible momentum going into the next decade, and to build new collaborations.

Raising the Bar to Help More Melanoma Patients

While some newly approved treatments are helping far more patients with advanced melanoma hit the five-year survival threshold, there are still too many patients who don't respond to these treatments, and others who may respond, but don't maintain a durable response. The bar has been raised for many, but further work is needed to raise the bar for more melanoma patients.

Driving this need home, Grace Wenzel provided opening remarks via an address delivered from her hospital bed, recorded the night before the Retreat. Twenty-three-year-old Grace relayed how current treatments

On May 8, 2020 — two months after delivering the opening remarks at the MRA Scientific Retreat — Grace Wenzel passed away due to complications from melanoma. Grace's advocacy for melanoma research, prevention, and early detection continues to inspire. She will always be a cherished member of the MRA family.

put her melanoma into remission for several months, but now were no longer working. She pleaded with researchers to continue to strive towards a melanoma cure. “I have no idea what things are going to look like for me even one week from now. But I am determined to keep fighting.”

Delivering the Retreat’s opening scientific keynote, Jedd Wolchok of Memorial Sloan Kettering Cancer Center started by saying, “We are determined and by Grace’s side to help find better answers to her disease.” He and other researchers at the retreat reported on exciting results that they think will help maintain the amazing momentum. By assessing ways to improve existing therapies, including using them in combination or using them in patients with earlier stages of disease, as well as exploring totally new treatment avenues, researchers are optimistic that fewer patients will find themselves in circumstances similar to Grace. While many researchers focus on treatment, others are pursuing ways to prevent new melanomas or to detect them at an earlier stage. The hope is that by the end of this decade, if not sooner, patients like Grace will not be in the hospital, but will instead be leading normal lives after successful melanoma treatment. Better yet, there may be fewer melanoma patients altogether because of successful and widespread melanoma prevention programs.

Jedd Wolchok of Memorial Sloan Kettering Cancer Center delivers the opening scientific keynote

The Treatment Landscape

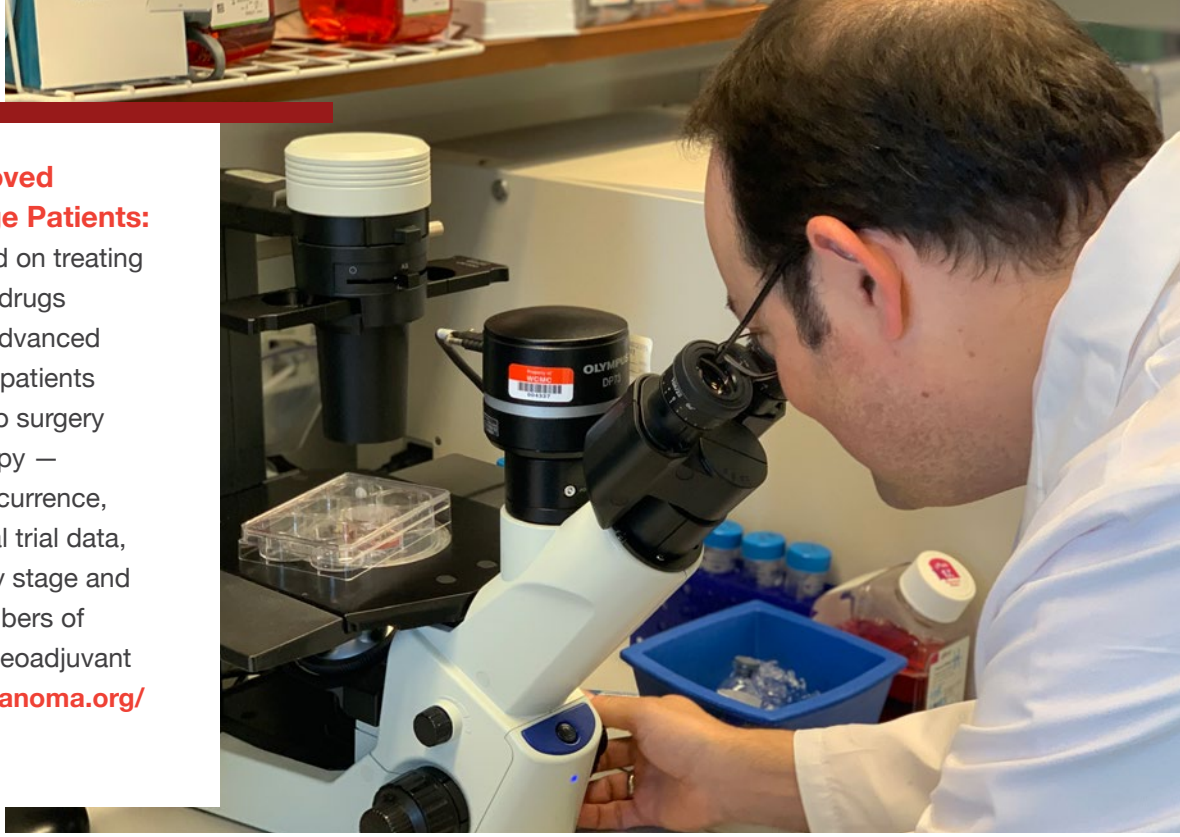
Immunotherapies, Combinations & Dosing: Currently, thousands of clinical trials are testing new combinations of immunotherapies in melanoma and other cancers. Most build on already approved checkpoint immunotherapies by adding to them vaccines and other new agents designed to rally more components of the immune system to enhance overall response. Others combine them with standard chemotherapy, targeted therapy, or radiation therapy. “Combination therapy will be necessary for immunotherapy to achieve its full potential,” Wolchok stressed. The experimental combination therapies build on the greater understanding of immune responses to tumors that has blossomed from basic research. “These are rational immunotherapy combinations based on rational preclinical science, rather than just throwing things out and seeing what sticks because there are too many possible combinations to try,” Wolchok noted.

“There shouldn’t be a one-size-fits-all assumption about dosing.”

— Jedd Wolchok

He added that investigators are also becoming more refined in the dosing of immunotherapies as they gain a better understanding of how the therapies work on a molecular level. Given the severe adverse reactions often caused by immunotherapies, “There shouldn’t be a one-size-fits all assumption about dosing,” he said. Wolchok described one study (NCT03122522) testing “**adaptive dosing**” that uses an innovative imaging agent to detect how patients are responding after just two doses of combination ipilimumab + nivolumab therapy. Building on the understanding that responses to combination ipilimumab + nivolumab often continue even if ipilimumab is discontinued, continuation of the combination therapy in the trial was based on whether a response to therapy is seen after just two doses. Only patients who do not appear to be responding well — as detected by medical imaging — continue to receive combination therapy. Patients whose tumors are

Bringing Currently Approved Therapies to Earlier Stage Patients: Researchers are also focused on treating earlier stage melanoma with drugs currently approved only for advanced melanoma patients. Treating patients with systemic therapy prior to surgery — termed neoadjuvant therapy — may reduce the chance of recurrence, which is supported by clinical trial data, although these trials are early stage and have enrolled only small numbers of patients. Learn more about neoadjuvant therapy here: **www.CureMelanoma.org/NeoAdjuvantWorkshop**



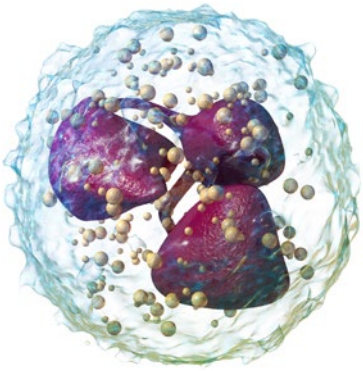
Jonathan Zippin of Weill Cornell

responding switch to nivolumab only. This approach offers the potential to further mitigate some adverse events. Wolchok also highlighted that researchers are developing sensitive genetic tests that can detect whether melanoma cells are still present in the blood of patients who appear to be in remission (often referred to as liquid biopsies), and therefore may warrant continued treatment despite no evidence of disease.

Novel Therapies that Reduce Off-Target Effects: Other researchers, such as Rizwan Haq of the Dana-Farber Cancer Institute, are striving to find a way to design targeted therapies that avoid harmful effects on healthy cells. Molecularly targeted treatments inhibit growth-promoting enzymes called kinases, but in many cases, healthy cells also depend on these enzymes, leading to toxic side effects. Haq's team identified a compound that inhibits an enzyme required for the survival in both melanoma and healthy cells. However, this drug is uniquely active in melanoma cells since it requires a chemical reaction to turn it 'on' that can only happen in tumor cells. Although further testing is needed, the compound could inhibit a kingpin growth pathway for melanoma cells not targeted by current drugs, without causing undue harm to normal cells. Haq found the compound suppressed the growth of melanoma cells in mice without causing harmful side effects for the animals, but these findings have yet to been verified by human tests. Haq noted that similar inhibitors for other growth promoting pathways in melanoma could be developed into safer drugs if they also are activated in this manner.

Immunotherapy Beyond Checkpoints: Investigators are also pursuing personalized treatments that rely on removing tumor-killing T cells from a patient, expanding them in culture, and then reinjecting them back into the patient, often referred to as TILS (Tumor-Infiltrating Lymphocytes). Similarly, another "adoptive T cell" approach is to remove a patient's T cells and genetically engineer them to hone in and attack tumor cells better. Both types of experimental treatments are currently being tested in clinical trials and may be especially useful to treat patients with rare subtypes of melanoma, which tend not to respond as well to current therapies.

Scientists are also exploring ways to call more types of anti-tumor immune cells to action. Spread of a tumor after responding to immunotherapies often occurs due to the outgrowth of tumor cells that lack the highly specific antigens T cells have been trained to attack. Immune cells called neutrophils and natural killer cells may be able to prevent such escape, Wolchok and Nick Huntington of Monash University both reported. This may be particularly true for so-called 'heterogeneous tumors,' which are composed of cells sporting different antigens on their surface — meaning that cells within the same tumor or in



3D model of a neutrophil

different tumors in the same person may look different to the immune system. Checkpoint immunotherapies work by releasing the breaks on T cells, spurring them to action. But as Wolchok noted, "T cells by themselves are only enough to kill tumors when you don't have to worry about heterogeneity. When you do, you need the neutrophils for an anti-tumor response. Neutrophils are underappreciated—they are considered poor stepchildren in immunotherapy—but they deserve our attention." Using a mouse melanoma model, Wolchok presented data suggesting that neutrophils create an inflammatory environment that works in conjunction with T cells to eliminate heterogeneous tumors.

Natural killer (NK) cells may also be a key target to pursue as studies in mice reveal that these cells prevent melanoma from metastasizing when injected intravenously, presumably by being less selective than T cells in attacking tumor cell antigens. Huntington pointed out that although T cells outnumber NK cells in tumors, there are more NK cells that can specifically recognize and target melanoma cells in tumors, compared to T cells. Underscoring a potentially tumor-fighting role for these cells, patients with high numbers of NK cells tend to have more favorable outcomes. Because they drive T cells and other immune cells to infiltrate the tumor, he added, NK cells are likely to make melanoma more responsive to already approved immunotherapies. Huntington's recent research has revealed key molecules that control natural killer cells' ability to target and kill tumor cells, and efforts are underway to develop drugs that act on these molecules so as to create a new type of immunotherapy for melanoma that could be used singly or with already approved treatments.

Thorsten Mempel of Massachusetts General Hospital reported on another way to potentially enhance existing immunotherapies. He found a molecular pathway in mice for converting T regulatory cells — immune cells that typically suppress an immune response to tumors — into T cells that promote tumor killing. If these findings can be translated into a safe drug that stimulates this pathway, it could be used to enhance current immunotherapies by lifting another brake on the immune system.

Improving Treatment Outcomes with Lifestyle Changes

How Lifestyle Can Impact Treatment: Though immense progress with new treatments has been made, and further research offers additional hope, it is widely understood that treatment is only one part of the equation. Lorenzo Cohen, a melanoma survivor and research psychologist at the University of Texas MD Anderson Cancer Center stressed the need to focus research on lifestyle factors that can help improve patient response to treatments. "Love, support, sleep, exercise, and diet impact all the cancer hallmarks we're trying to harness as drug developers," Cohen pointed out. He cited studies indicating that chronic stress suppresses immune responses, while exercise increases immunity.

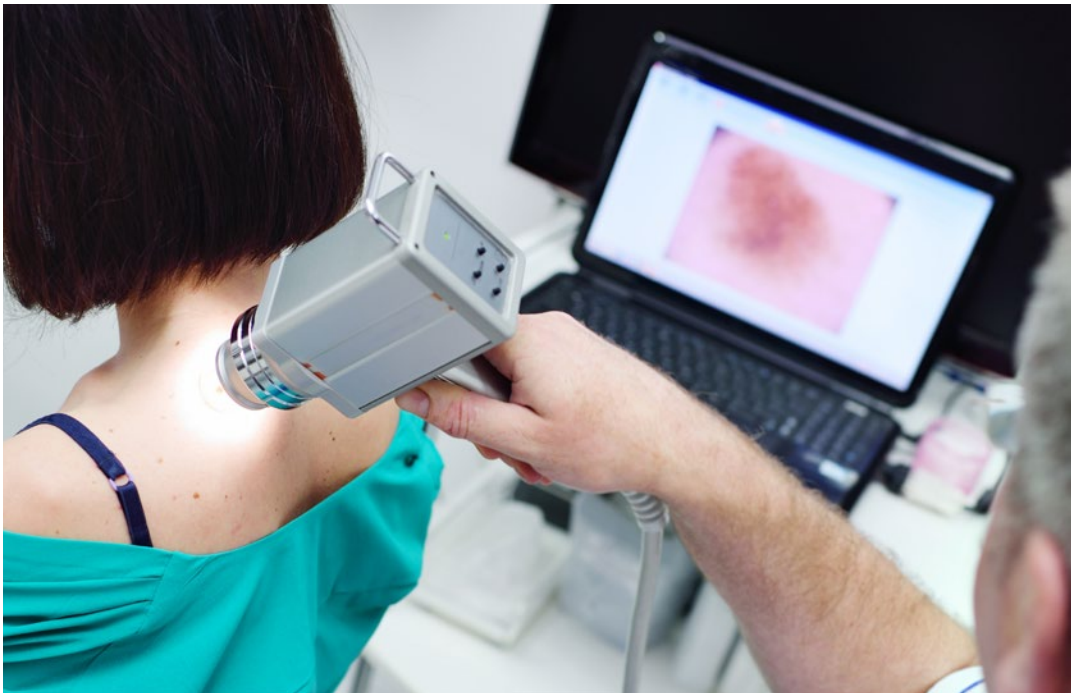
Diet is also important to melanoma patients receiving immunotherapies as preliminary studies show patients with the highest fiber in their diet are more likely to

Lorenzo Cohen of University of Texas MD Anderson Cancer Center

"Engaging patients is key to maximizing the benefits of treatment and getting the best long-term response."

— Lorenzo Cohen

respond to them, likely because of the effects of fiber on the gut microbiome. Much of this research is still in its early stages, however, so it's challenging to come up with definitive lifestyle recommendations for current patients, he noted. Cohen stressed that, "Engaging patients is key to maximizing the benefits of treatments and getting the best long-term response." He suggested using technology, such as streaming, video chatting, and online groups to help patients make healthy lifestyle changes. "We can use technology to beam into patients' homes information on cooking and exercising," he noted.



Bringing Melanoma Prevention to the Forefront: Even more progress could be made if melanoma was prevented from occurring to begin with, Susan Swetter of Stanford University pointed out. Noting that sunburns heighten the risk of developing melanoma, she said "If we enacted a comprehensive prevention program aimed at reducing ultraviolet light exposure, we could reduce melanoma by 20 percent and reduce $3 billion of costs in treating melanoma." Swetter noted that unlike in European countries, sunscreen ingredients haven't been improved in the US in the past several decades, and there are no full-spectrum sunscreens on the market. She pointed out that research is underway to develop other agents beyond sunscreen to prevent melanoma that reduce the damage induced by sunburns.

United States Surgeon General Jerome Adams

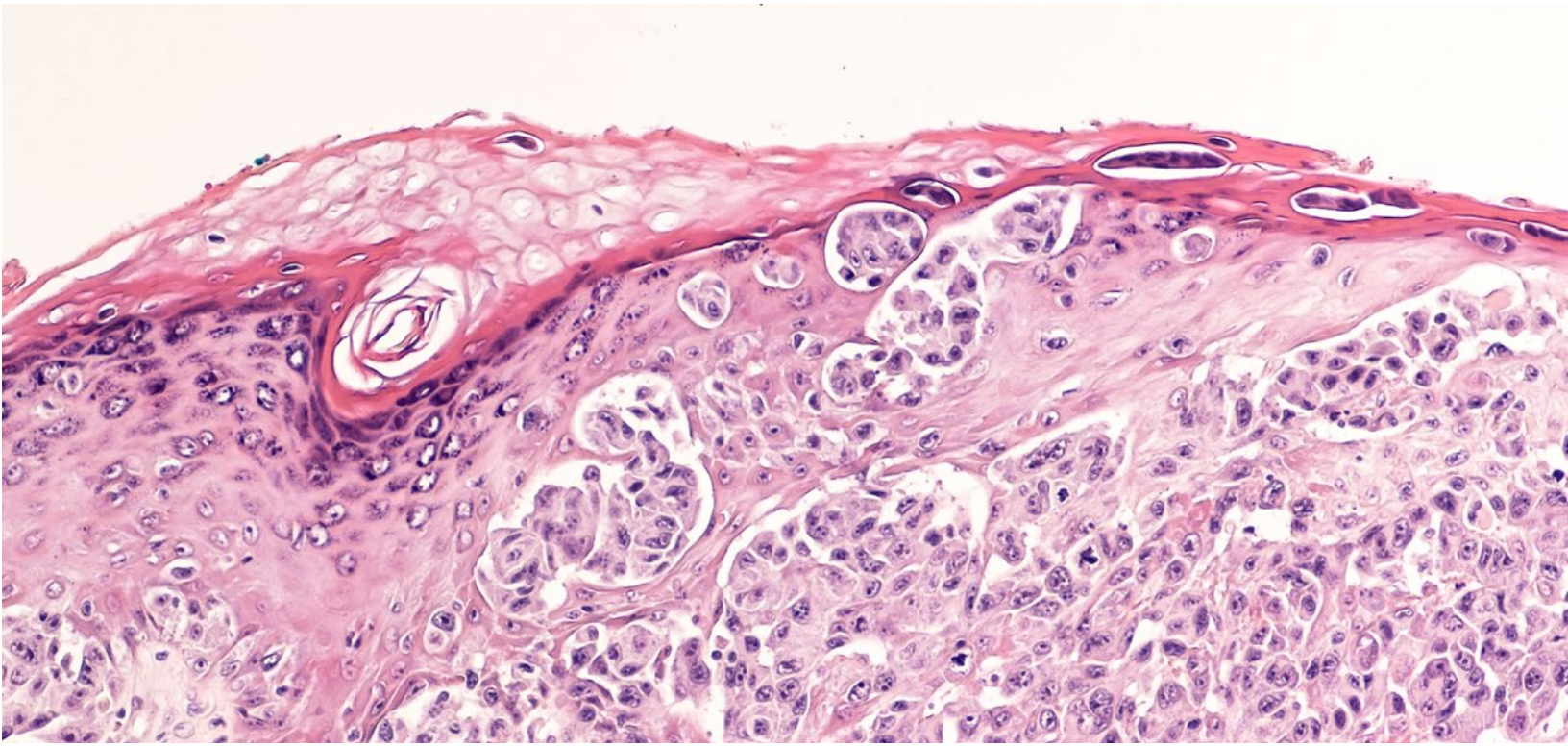
US Surgeon General Jerome Adams suggested restricting access to tanning facilities is also key to reducing melanoma incidence. He pointed out that although some tanning facilities have been limited by local or state laws, a national law in this regard is still needed. "As glad as I was that there was top notch research to help my wife deal with a deadly melanoma, I still wish I could have gone back in time and told her not to get into that tanning bed," he said at the MRA Patient and Advocate Forum.

Adams recently updated the Surgeon General's 5-year plan to emphasize prevention of skin cancer, but he reported that a million high school students continue to use indoor tanning devices, and each year half of adults and high school students get sunburned. He suggested more public health measures aimed at preventing sunburns, including increasing shade in playgrounds, recreation areas, and other public spaces, and increasing public education efforts about sun safety so that sun protection becomes a habit. "No matter how many great drugs there are for melanoma, that won't change the fact that for every person we cure, 10 more are going to get it," he stressed.

Basic Research:

Understanding what Triggers Melanoma and its Spread to Identify New Treatment Targets

Basic Research



Tremendous progress has been made in understanding the basic biology needed to trigger melanoma and fuel its growth and progression. These findings have led to the targeted therapies we have today for melanoma patients that target the proteins BRAF and MEK (with BRAF mutations are seen in about half of cutaneous melanomas). But because not everyone responds to these treatments and those that do tend to relapse, researchers continue to probe deeper, finding new molecular culprits that could lead to novel and more effective melanoma treatment strategies. Some of these new potential drug targets were revealed at MRA's 2020 Scientific Retreat.

How Melanocytes Turn into Melanomas

Lorenz Studer of Memorial Sloan Kettering Cancer Center has been investigating the process by which melanocytes, a type of cell that resides in the skin, turn into melanomas using both human stem cells and zebrafish models of melanoma. Studer has identified parallels between how stem cells differentiate — or transform — into melanocytes and how melanocytes can morph into melanomas. His studies reveal that similar genetic programs operate in both of these cellular processes and identified a particular protein that leads to changes in melanocyte metabolism, growth, and movement that enables the transformation of these cells into a melanoma. Melanoma patients whose

Lorenz Studer of Memorial Sloan Kettering Cancer Center

primary tumors express high amounts of this protein have worse outcomes. Although more validation studies are still needed, these studies point to a novel drug target that may prevent tumor formation. Studer suggested that other factors similar to the one he uncovered could play key roles in enabling melanoma to persist. “This is just the beginning as there could also be other similar factors needed for tumor maintenance that could be targeted by treatment,” Studer stressed.

Elaine Fuchs of Rockefeller University

Research conducted by Elaine Fuchs at the Rockefeller University is also focused on how melanomas initiate. In particular, she is studying the melanocyte stem cells — these are cells of the skin that perpetually self-renew, creating cells that eventually mature into melanocytes — the cell type that gives rise to melanomas. Fuchs thinks studying these stem cells may be important because her studies on squamous cell carcinoma — another type of skin cancer — have revealed that the stem cells of the skin that give rise to those tumors are often treatment resistant and contribute to relapse and metastasis. Tumors are often surrounded by blood vessels and attract immune cells. Fuchs’ studies show that these inputs can cause the tumor’s stem cells to be active and invasive. “We think that the tumor stem cells also enter these blood vessels and cause metastasis,” Fuchs offered. Fuchs’ early studies suggest something similar may be happening with melanoma. She continues to explore this with the hopes of developing compounds that can block the signals that activate the stem cells, thereby preventing metastatic spread, disease relapse, or recurrence.

The Role of RNA in Melanoma Formation

Other researchers are exploring sections of the genetic RNA machinery in our cells and how they might contribute to melanoma. RNA is best known for being the intermediary between the DNA that makes up our genes and the proteins that these genes give rise to. But there is a lot of RNA in cells that does not participate in this process, and for a longtime, scientists thought it was unimportant for cellular functions — so much so that it was often referred to as “junk” RNA. But now it appears that these “junk,” or more accurately ‘noncoding,’ regions of RNA are rife with specific variations that appear to govern the initiation, growth, and even the spread of tumors, including melanomas. “I hope I can convince you that these noncoding regions are not garbage,” stressed Eleonora Leucci of the KU Leuven during her presentation.

She found a noncoding RNA molecule abbreviated SAMMSON that is expressed by most melanomas, but not normal melanocytes, and that promotes melanoma growth and survival. When Leucci blocked SAMMSON in melanoma cells, most died, including both BRAF mutant and non-BRAF mutant cells, suggesting SAMMSON may represent a broad drug target for melanoma. Reducing SAMMSON expression increased the effectiveness of BRAF/MEK inhibitors in melanoma mouse models, and even worked to slow the growth of tumor cells resistant to BRAF/MEK inhibition. These findings suggest that a compound that targets SAMMSON could be effective in melanoma patients in combination with BRAF-targeted treatment, and because SAMMSON is not found in normal cells, this compound may cause few serious side effects. “This would be beautiful,” Leucci said, but added that

unfortunately, there are no agents targeting SAMMSON that are approved yet in the clinic.

Interestingly, SAMMSON acts on some of the same cellular signaling pathways that a specific class of FDA-approved compounds do, leading Leucci to suspect they might also be effective in killing melanoma cells. Testing this in mice by combining the compounds with BRAF/MEK inhibition, as well as with immunotherapy, suggests this may be a promising therapeutic strategy; however, more follow-up studies are needed before testing this in patients.

Florian Karreth of the Moffitt Cancer Center also focuses his research on the noncoding regions of RNA, in this case on regions that are thought to indirectly fine-tune protein production and play a role in melanoma growth and progression. He found one short stretch of RNA, called miR-29, that when inactivated enhanced production of melanoma tumors in mice. Further analysis revealed that loss of miR-29 promotes melanoma because it leads to increases in the production of protein MAFG, which is normally shut off by miR-29. "Melanoma cells are addicted to miR-29 inactivation and overproduction of MAFG," Karreth said. He also found three genes that affect the activity of miR-29 and other short noncoding regions of RNA. When these genes were overactive, they promoted melanoma metastasis in mice. "Understanding the mechanisms of non-coding RNAs has the potential to uncover novel targets for therapy," Karreth stressed.

All this basic research on what causes melanoma to start, and then eventually progress, has the potential to lead to more effective melanoma treatments, but translating these findings into something usable in the clinic can take many years, noted Rizwan Haq of the Dana-Farber Cancer Institute. At the **Patient and Advocate Forum**, he pointed out the lack of new melanoma treatments in what some call a drought period between 1975 to 2010, prior to the explosion of new treatments in the decade following. He stressed that "If we look at the pre-clinical lab work that directly led to the development of these therapies approved since 2010, it was [conducted] during this so-called drought. Research is the engine we need to support in order to drive the next generation of innovation and treatment."

"Research is the engine we need . . . to drive the next generation of innovation and treatment."

— Florian Karreth

Florian Karreth of the Moffitt Cancer Center

Advancing Acral Melanoma Research:

New Drug Targets for Rare Types of Melanoma

Advancing Acral Melanoma Research

Modeling melanoma in zebrafish has led to important new insights about melanoma development, progression, and treatment

Patients with acral melanoma, a rare subtype of the disease that develops in the nailbeds, palms, or soles of the feet are particularly underserved by today's treatments. For example, the BRAF mutations found in about 50% of cutaneous melanoma cases are only seen in approximately 25% of patients with acral melanoma. Thus, only a small subset of patients with acral melanoma are treated with targeted therapies such as combination BRAF/MEK inhibitor drugs. Patients with acral melanoma also tend not to respond as well to checkpoint immunotherapies. So, raising the bar on improving outcomes for all advanced melanoma patients will, in part, depend on developing new treatments for acral and other rare subtypes of melanoma like uveal and mucosal melanoma. Those treatments, in turn, will depend on more research on these subtypes that deepens our understanding of what causes them or enables them to flourish. "We need to extend the advances in cutaneous melanoma to other subtypes that respond less robustly," stressed Richard Carvajal of Columbia University during a panel discussion at the 2020 MRA Scientific Retreat.

Fortunately, recent studies on acral melanoma that were presented at the 2020 MRA Scientific Retreat are showing promising findings.

Raising the bar on outcomes for advanced patients depends on developing new treatments for rare types of melanoma.

Richard White of Memorial Sloan Kettering Cancer Center

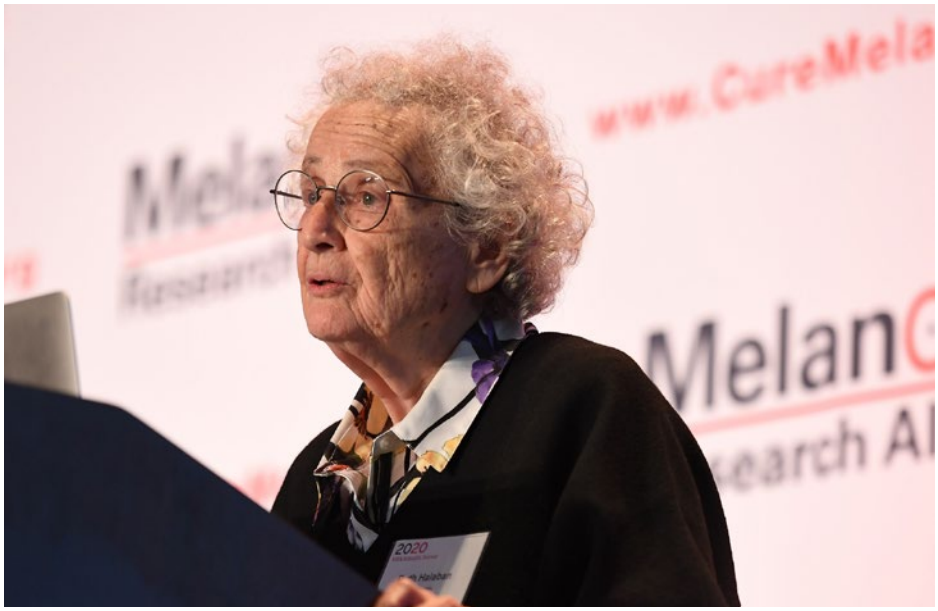
This research reveals some of the unique genetic flaws underlying this type of melanoma and how they interact with other factors in the body to trigger tumors and their growth. These basic research findings suggest new drug targets that could be particularly effective for patients with this melanoma subtype.

Richard White of Memorial Sloan Kettering Cancer Center shared findings — based on an innovative zebrafish model — that help explain why acral melanoma only occurs on the hands and feet. He created this model by giving the fish the same genetic defects found in acral tumor samples. Strikingly, he found these fish develop melanoma tumors predominantly in their fins, which are evolutionarily related to limbs in people. These findings suggest the cells that generated them are stamped early in development with a molecular signature unique to the fin/limb position in the body to which they migrated. That signature is retained and dictates unique molecular signaling pathways and susceptibilities for their particular locale on the edges of the body. "Something in the microenvironment in the fin or limb synergizes with the gene signatures common to acral melanoma to drive this type of melanoma," White stressed.

Building on knowledge of the gene that plays a role in localizing acral melanoma development to the fin/limb, White noted that when he knocked out the gene's activity in his zebrafish, they no longer developed melanoma on their fins or on any other part of their body. "Targeting this gene may offer new therapeutic opportunities in acral melanoma," White concluded.

Boris Bastian's research at the University of California, San Francisco suggests that proteins involved in the repair of DNA may be another target for future acral melanoma treatments. Bastian's genetic analyses of acral patient tumors suggest that many of these rare melanomas may also be triggered by major genetic rearrangements due to DNA breaks that aren't repaired due to mutations in genes that carry out this function in cells. Because repairing DNA — even if the job is imperfect — is critical for cell survival, cells use multiple processes to do this. Bastian thinks that blocking the remaining functional DNA repair pathway in acral melanoma may prove to be its Achilles heel, and is currently conducting laboratory experiments to explore this hypothesis more thoroughly.

Ruth Halaban of Yale University and Aaron Newman of Stanford University reported on their discovery of another potential drug target for acral melanoma—a gene located in a specific stretch of DNA that tends to be duplicated multiple times in acral melanoma. In studies of acral melanoma cells cultured in the lab, suppressing this gene reduced tumor growth. Little is known about the role of this gene in melanoma, and so Halaban and Newman are also working to identify how it contributes to acral melanoma initiation and progression.



Ruth Halaban of Yale University

Phyu Aung of the University of Texas MD Anderson Cancer Center

"We need to figure out how to get the most information out of a small group of patients."

— Richard Carvajal

Proteins in cells that control the activation of certain cancer-causing genes may also play a role in acral melanoma. In her genetic and tissue studies of acral melanoma, Phyu Aung of the University of Texas MD Anderson Cancer Center found a flawed genetic activation pattern, called DNA methylation, of six genes that was linked to a worse prognosis in patients. She also found a subtype of acral melanoma that tended to have more T cells in tumor samples, suggesting it might respond better to existing immunotherapies.

The research updates presented at the 2020 MRA Scientific Retreat revealed many promising molecular leads for acral melanoma. Developing new experimental drugs, testing their safety and effectiveness among acral melanoma patients will be challenging given the relative rarity of this melanoma subtype. Acral melanoma is estimated to account for just 5% of all melanomas worldwide. "We need to figure out how to get the most information out of a small group of patients," Carvajal stressed. To do this, he suggested not further subdividing the small numbers of patients with acral melanoma into control and treatment arms, but rather comparing patients who are given an experimental treatment to how patients similar to them did in the past without such treatment. These can be achieved through patient registries, or prospective cohorts of patients with rare melanomas. He also suggested conducting multi-center clinical trials to capture enough numbers of these rare patients. Determining the best approach for bringing new therapies to patients with rare melanoma subtypes will require innovative science and input from regulatory officials, such as those at the U.S. Food and Drug Administration.

FIGHT BACK GIVE BACK

Without You Cures Can't Happen, Ask About a Clinical Trial Today

Melanoma clinical trials are research studies involving human volunteers that are designed to answer specific questions about new treatments for melanoma. The answers gained through the research helps doctors find new ways to improve outcomes for people with melanoma. **Without patient volunteers our entire medical research process would stop.**

MRA's **"Fight Back Give Back"** campaign highlights the importance of clinical trials in driving progress towards curing melanoma.

Learn more about clinical trials at **CureMelanoma.org/ClinicalTrials.**

Dr. James Allison

and the Path to More Effective Immunotherapies

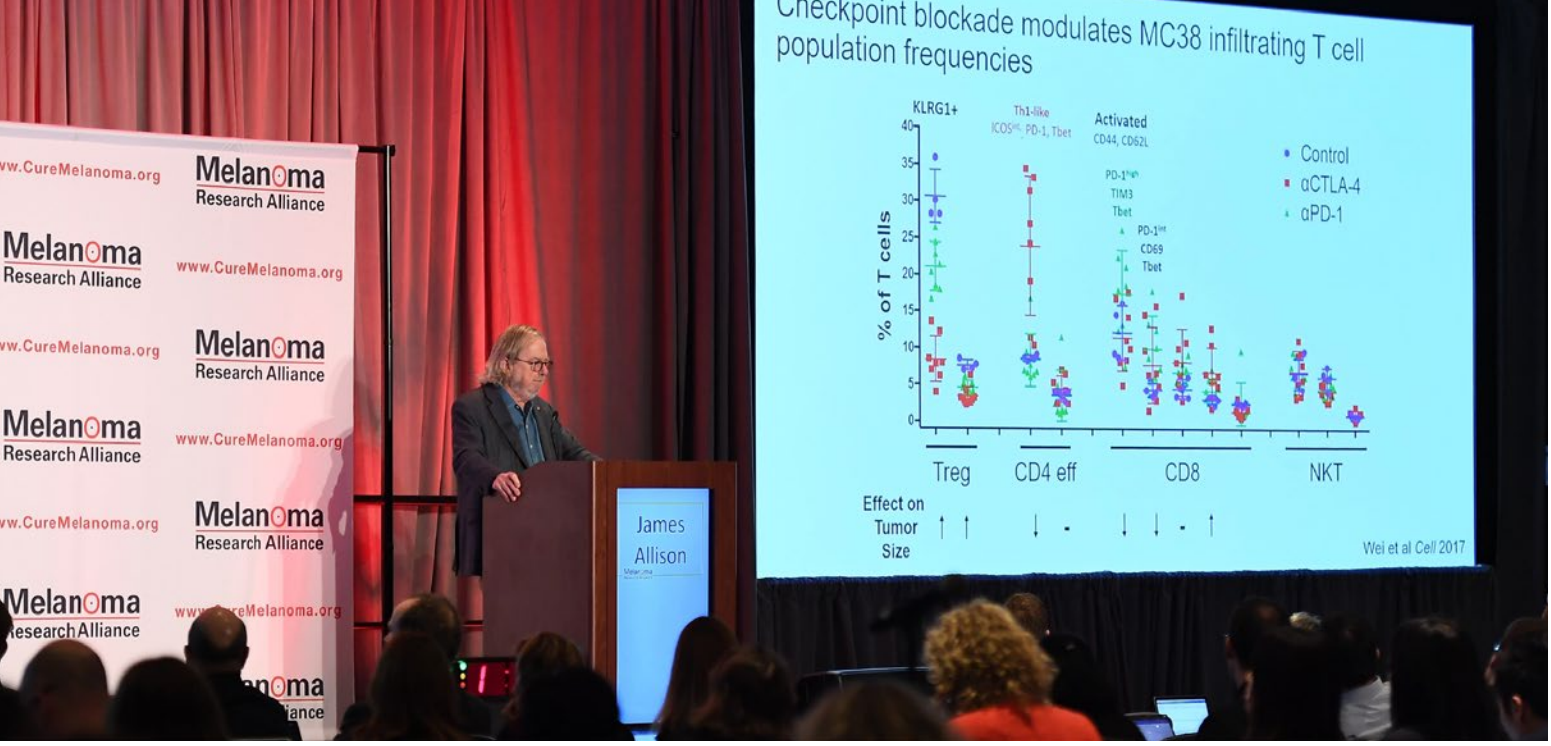
Dr. James Allison

When MRA co-founder and Board Chair Debra Black introduced James Allison of the University of Texas MD Anderson Cancer Center at MRA's 2020 Scientific Retreat, she described him as the man "who changed the way cancer patients are treated forever." This fitting introduction is due to Allison's pioneering work to mainstream the use of checkpoint immunotherapy as a tool in the arsenal against cancer; joining the likes of chemotherapy, radiation, and surgery. Dr. Allison and Tasuku Honjo were jointly awarded the 2018 Nobel Prize in recognition of their groundbreaking work on CTLA-4 and PD-1 checkpoint immunotherapies, respectively. These treatments release the brakes on T cells' response to tumors and have proven effective in treating, if not curing, millions of patients with advanced cancers.

"There's been a paradigm shift," said Allison's collaborator and wife Padmanee Sharma, also of MD Anderson. "It opened up a whole new field. Back in the 1990s, everyone laughed when we said we wanted to do cancer immunotherapy and only a handful of people attended sessions devoted to that at cancer research meetings. But then the field exploded with checkpoint immunotherapy."

"There's been a paradigm shift … it opened up a whole new field."

— Padmanee Sharma



James Allison of MD Anderson Cancer Center

From Dark Horse to Game-Changer

Decades before Allison began collaborating with Sharma, he had been conducting basic research on how the immune system works, with a major focus on T cells. Then in the mid-1990's, he was shocked when he went to check on mice given antibodies that blocked a recently discovered immune-suppressing protein called CTLA-4 found on the surface of T cells. The antibody had cured the mice of their cancers. "I was expecting anti-CTLA-4 to slow tumors a little bit, but the tumors completely melted," said Allison in an interview with the Journal of Clinical Investigation.

Inspired by those findings, and his brother who had been recently diagnosed with advanced prostate cancer, Allison doggedly pursued collaborators to develop his antibody into a drug that eventually would be called ipilimumab (Yervoy). But most major drug companies he approached were skeptical due to the poor track record of experimental cancer treatments that relied on the immune system to kill tumors. Despite seeing promising results in the lab, almost none of these treatments ended up working in patients, and of those that did, only a tiny fraction of patients benefited.

But ipilimumab proved to be a game-changer. Clinical tests of the drug showed it provided long-term complete remissions, which some call cures, in about one out of five patients with advanced melanoma. These were unprecedented findings — particularly because these responses were seen in patients with advanced disease — nearly all of whom would have failed to respond to treatments available to treat them at that time. Ipilimumab was approved in 2011 for advanced melanoma, followed shortly afterwards by drugs targeting another immune checkpoint called PD-1, discovered by Honjo. Checkpoint inhibitors have since been shown effective in treating many different types of cancers, including lung, kidney, colorectal, and bladder cancer.

CTLA-4- and PD-1-Targeting Immune Checkpoint Therapies Affect T Cells in Different Ways

But that is just the beginning of the story on checkpoint immunotherapies, Allison and Sharma stressed. They and many other investigators continue to search for more immune checkpoints that can be blocked, and thousands of clinical trials of various combinations of new and already approved immunotherapies are underway. "I never dreamed my research would take the direction it has," Allison said in an MD Anderson Cancer Center press release. "It's a great emotional privilege to meet cancer patients who've been successfully treated with immune checkpoint blockade. They are living proof of the power of following our urge to learn and to understand how things work." But Allison also stressed, "We need these drugs to work for more people. Our clinical success has outrun our scientific knowledge of how these drugs work and how they might best be combined with other therapies

to improve treatment and reduce unwanted side effects. We need more basic research to do that."

At the 2020 MRA Scientific Retreat, Allison reported on the abundant basic research findings on checkpoint blockers he and his colleagues have garnered recently. These reveal major differences in how anti-CTLA-4 and anti-PD-1 drugs affect an immune response to tumors, and why combining both types of drugs is especially effective. Allison found that blocking CTLA-4 affects the early stages of T cell activation and causes a wide range of new anti-tumor immune T cells to proliferate and become active. Blocking CTLA-4 also boosts production of the immune-stimulating protein, interferon-gamma. In contrast, blocking PD-1 acts on a different subset of T cells that do not produce interferon, and doesn't create new subsets of T cells. In addition, although anti-PD1 treatment expands these mature anti-tumor T cells, it also expands the number of so-called 'exhausted' T cells that cannot kill tumor cells. But when the two treatments are combined in laboratory studies, there is no expansion of exhausted T cells, and instead the combination activates a wider range of tumor-killing T cells subtypes and boosts interferon production. Understanding how each drug affects the immune system may allow for the design of improved versions of CTLA-4 and PD-1 antibodies, or new immunotherapy drugs altogether.

Padmanee Sharma, James Allison, and MRA Co-Founder and Chair Debra Black

Exploring New Combinations

"We need to improve survival by doing combination therapy," Allison stressed. He noted that in addition to combining anti-CTLA-4 treatments with anti-PD1 treatments, agents targeting other aspects of the immune response could also enhance current cancer immunotherapies. He and Sharma found a striking increase in T cells expressing the immunostimulatory protein ICOS in the tumors and blood of patients responding well to ipilimumab. Higher levels of ICOS were linked to greater survival among melanoma patients, and when a vaccine targeting ICOS was given to mice with melanoma, along with anti-CTLA4 treatment, it increased the effectiveness of CTLA-4 blockade. "There are many other immune checkpoints besides CTLA-4 that contribute to immune resistance pathways and we need to understand where and when they play key roles," Sharma said.

Fortunately, many investigators in addition to Sharma and Allison are devoted to uncovering this information in their labs, now that such basic immunology research has proven its worth in leading to effective treatments for advanced cancers. "Improving survival with immunotherapies can be done," Allison said. "And understanding the molecular mechanisms gives us a handle on how to do it."

"Improving survival with immunotherapies can be done... Understanding molecular mechanisms gives us a handle on how to do it."

— James Allison

Industry Roundtable

Bringing Industry Together to Break the Barrier

2020 Industry Roundtable

From left: Marc Hurlbert, Patrick Hwu, Marc Theoret, Steven Lemery, Charlotte Ariyan, and Art Krieg at the 2020 Industry Roundtable

Although the media tend to highlight patients such as President Jimmy Carter, whose metastatic melanoma seems to have been cured by a cancer immunotherapy, Dr. Patrick Hwu opened the Industry Roundtable Breakfast discussion at the 2020 MRA Scientific Retreat by noting a 21-year old patient with advanced melanoma he recently treated who only survived three months. “We gave him everything we could, including immunotherapy and it was tragic,” Hwu said. The patient was typical of those with a high burden of rapidly progressing disease who tend not to respond to the newer targeted and immunotherapies that have proven so effective in others with metastatic melanoma. “We haven’t raised the mark for these patients,” Hwu stressed.

Response rates have not improved much over the past 10 years for most patients with rare melanoma types.

Response rates have also not improved much over the past 10 years for most patients with rare melanoma subtypes, such as those with tumors that crop up in the eye, mucosal membranes, or the hands and feet. For these reasons, the MRA brought together key experts from drug and biotech companies, the Food and Drug Administration (FDA), and academia at the Annual Industry Roundtable to explore how to improve the long-term survival rate for the half of patients with advanced melanoma who do not respond to currently available treatments. Among

MRA Chief Science Officer Marc Hurlbert and Patrick Hwu of University of Texas MD Anderson Cancer Center

"We need to nail down the basic science and biological understanding for rare subtypes of melanoma."

— Patrick Hwu

the suggested options were developing new tests or types of imaging to predict a patient's response to treatment, improving clinical trial designs and patient access to them, and conducting additional basic science research to answer remaining unanswered questions such as how existing treatments work, why only some patients respond to them, and why others relapse.

Identifying Biomarkers to Predict Response

If new and more predictive biomarkers could be identified to help assess which patients would respond best to which treatment, patients who have little chance of success with certain treatments could be quickly funneled into alternative treatment options or to clinical trials of experimental therapies that might be more effective. Marc Theoret of the FDA pointed out that such 'biomarker' tests could possibly enable enriching a clinical trial population with patients at high risk of progressing, making it easier to detect a clinical benefit of an agent or combination of agents in this high-risk population. By enriching a patient population through use of a biomarker, it is possible to accelerate the clinical trial process for these patients.

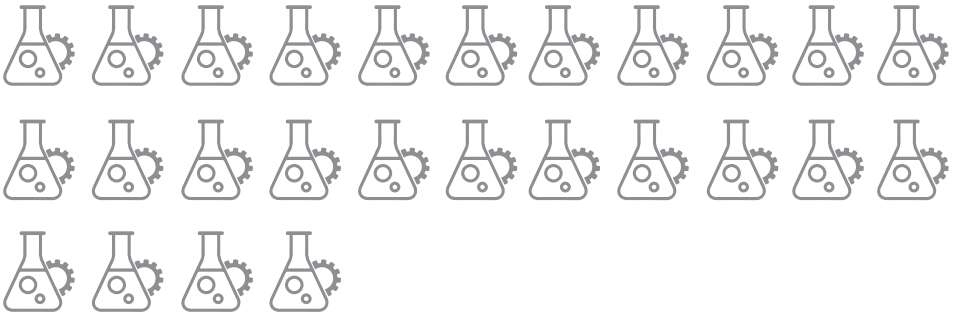
Although investigators are currently testing levels of an enzyme called LDH and other potential biomarkers of high-risk patients unlikely to respond to current therapies, as well as biomarkers and imaging tests that can indicate an early lack of response to immunotherapies, clinicians don't know yet "who to give what," Hwu noted. Federico Monzon of Castle Biosciences pointed out that such diagnostics have not yet been developed because of a lack of knowledge of molecular defects, akin to mutant BRAF, predicting response to certain treatments, and especially for immunotherapies. Similarly, biomarkers to detect early response to immunotherapies, before tumors can be seen to shrink using traditional imaging tests, are lacking. Howard Kaufman of Replimune stressed that "we need to put more biomarker studies in all our industry and academic investigations to help guide targeting the specific defects in individual patients."

Dr. Suzanne Topalian of Johns Hopkins University noted the utility of clinical trials in which therapeutic agents are given to melanoma patients before their tumors are surgically removed — termed neoadjuvant therapy. These studies enable researchers to compare before and after treatment tumor samples for molecular or cellular signals or patterns indicating response or lack of a response, which may then serve as biomarkers for future patients. Such neoadjuvant treatment in patients with early-stage melanomas might also help prevent them from progressing to more advanced and difficult to treat stages. Hwu suggested giving neoadjuvant treatment to patients with Stage 2 melanoma because more people die from melanomas originally diagnosed in this thin-lesion stage than those diagnosed with thicker tumors that are generally treated more aggressively. This is because there are a much greater number of melanoma patients with thin as opposed to thick lesions at diagnosis. But mandating such biopsies is difficult to do for studies supported by the National Cancer Institute because there often is no additional funding set aside for tissue removal and analysis, one participant noted. "Where do we get that funding for biomarkers and correlative science?" was asked by many participants.

MRA's Industry Roundtable

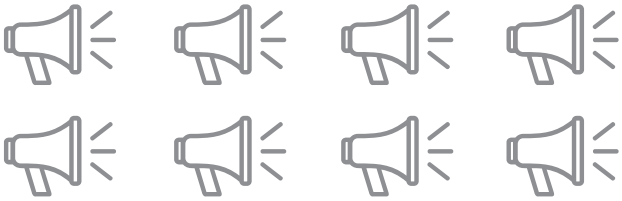
Each year, at the MRA Scientific Retreat, representatives of each biotech and pharma sponsor are convened together with key opinion leaders, and government representatives to discuss, and hopefully advance, current challenges in the field. In 2020 — the Roundtable included representatives from 26 companies, and was focused on improving long-term survival for patients with advanced melanoma.

26
Pharmaceutical & Biotech Companies



6
U.S. Government Representatives

8
Key Opinion Leaders



Icons: Megaphone by NOVITA ASTRI from the Noun Project | Government by bezier master from the Noun Project

Expanding our Knowledge of the Tumor-Targeting Immune Response

The development of some diagnostic tests will also hinge on gaining a more granular understanding of the immune response to tumors and how it differs between patients that respond to immunotherapies and those that don't. As Antoni Ribas of the University of California, Los Angeles noted, some patients may not respond to checkpoint immunotherapies because tumor-killing T cells present in their blood may not be able to reach the tumor. These patients might respond better to a drug that directs these T cells to tumors. "Patients who don't respond to anti-PD-1 therapy might get a response to another immune-based therapy," he said. Professor Richard Marais of the Cancer Research UK Manchester Institute added "We need a better understanding of what is happening in the tumor microenvironment. If we understand why those T cells are not doing their job, we can tackle it better with treatments."

Topalian suggested being even broader in our pursuit of basic information about an immune response to tumors so as to break the 50-percent barrier. "What is preventing

advances is a lack of scientific knowledge. We're still focusing on T cells and antigens, but we don't know the whole story." She noted that researchers in the past have not provided enough focus on the important role antibody-producing B cells play in an immune response to tumors that recent studies are now highlighting. "We need to leap into a completely new area of knowledge," she stated.

Kellie Malloy of OncoSec Medical noted several efforts to enhance currently approved immunotherapies, including intratumor vaccines that don't appear to have any overlapping toxicities with approved checkpoint inhibitors. "They offer a different immune-targeting pathway and we have to bring every tool and type of ammunition to the fight," she stresses.

Improving clinical trial designs

Malloy and others also suggested improving clinical trial designs so that multiple agents can be tested simultaneously in adaptive trials, similar to the I-SPY trial in breast cancer patients. This trial enabled nonresponding patients to be switched to new experimental treatment arms within the same trial based on their early response results. Caroline Robert of Gustave Roussy Institute also stressed that improvements could be made with the approved treatments we already have by improving clinical trial designs to better test how to use existing options in combination, with alternative doses, or sequencing to compare their effectiveness. Such trials can be challenging to forge though, Hwu noted, because they require the cooperation of multiple drug companies.

Kellie Malloy of OncoSec

"[Immunotherapies] offer a different immune-targeting pathway and we have to bring every tool and ammunition to the fight."

— Kellie Malloy, OncoSec

Greater cooperation in the arena of sharing patient data in the public domain could also help move the field forward, Michael Meyers of Syndax pointed out.

Focusing on the Biology of Rare Melanoma Subtypes

MRA's Chief Science Officer, Marc Hurlbert, and others stressed the need to focus on patients with rare subtypes of melanoma that tend to not respond well to current therapies. Steven Lemery of the FDA pointed out that patients with uveal melanoma, which develops in the eye, have difficulty accessing clinical trials because the drug industry expects a lower response rate from them. He suggested including these patients in trials as a preplanned subset, but not including them in the primary analysis of results, may be one way forward for this rare melanoma subtype. If a secondary analysis finds that people with the more common cutaneous melanoma as well as those with uveal melanoma respond to a treatment, labeling could then be expanded to include the latter group. Charlotte Ariyan of Memorial Sloan Kettering Cancer Center stressed that not all forms of melanoma share the same pathology and "the more we do basic science research on these subtypes, the more drug companies will develop agents to target them." Hwu agreed that, "we need to nail down the basic science and biological understanding for rare subtypes of melanoma."

Expanding Clinical Trial Enrollment

Another participant noted that key to improving outcomes in melanoma is having more melanoma patients participate in clinical trials of new treatments, but that many trials have trouble accruing sufficient numbers of patients. Accrual for immunotherapy trials could be expanded,

Marc Theoret, Steven Lemery (center) and Charlotte Aryian

the participant said, if patients with autoimmune disorders are no longer automatically excluded from participating. Such exclusions were historically thought to be warranted because patients can develop severe autoimmune conditions in response to therapies that rev up their immune systems; but given that clinicians have become more adept at managing these immune-related adverse events, such exclusions may no longer be warranted, especially for melanoma patients with no other options.

Breaking the barrier –making long-term survival possible for even more patients with advanced melanoma — will require all stakeholders to continue their life-saving work needed to improve existing and to develop altogether new approaches to treating melanoma. Better understanding the melanoma biology and immune response, improving clinical trial designs, and keeping rare melanoma subtypes at the forefront are key strategies that will carry the melanoma community through the next decade of research.

Lola Fashoyin-Aj of the Food & Drug Administration

Young Investigators Lead the Path Forward

Advancing Immune Checkpoint Therapy and Exploring Nanotechnologies

Young Investigators Lead the Path Forward

Since issuing its first research award in 2008, the Melanoma Research Alliance has held steadfast to the belief that pulling early career scientist with novel ideas into the field of melanoma could provide substantial impact on innovation and help drive the field forward. Since 2008, MRA has invested nearly $20 million through 115 Young Investigator awards as of the end of 2019, and an additional 79 young investigators were supported within Team Science Awards.

Among MRA's inaugural class of Young Investigators, Dr. Padmanee Sharma has demonstrated what early investment can do for both the field and an investigator. Dr. Sharma was funded in 2008 as she worked to further the understanding of checkpoint immunotherapy well before there had been an FDA approval for such treatments. Twelve years later, at the 2020 MRA Scientific Retreat, Dr. Sharma provided a keynote lecture on investigating the response and resistance mechanisms to immune checkpoint therapy, a field she has helped to advance. This work has led to her to identify several potential new drug targets to test in combination with ipilimumab, some of which are currently in clinical trials.

Since 2008, MRA has invested nearly $20 million through 115 Young Investigator awards.

Padmanee Sharma of University of Texas MD Anderson Cancer Center

Sharma's "clinic to lab and back again" research approach allowed her to uncover other key players in anti-tumor immune response.

The innovation and novel approaches brought in by Young Investigators, were further highlighted at the 2020 Retreat in a talk given by Dr. Ashish Kulkarni of the University of Massachusetts, a 2017 Young Investigator Award recipient who is applying his engineering training to develop new melanoma treatments and imaging techniques.

Supporting the Next Generation of Melanoma Researchers

Young Investigator Awards, which are given to scientists within four years of their first academic faculty appointment, attract early career scientists with novel ideas into melanoma research. This seed funding comes at a critical time for these researchers, who are just starting to establish their own independent research labs and focus areas. Such funding typically grows researchers' careers by allowing them to hire personnel and generate data needed to attract more traditional sources of funding, like that from the National Institutes of Health. By providing an early runway towards melanoma research with guaranteed funding, MRA's Young Investigator Awards help to steer promising talent towards a career focused on melanoma.

Dr. Sharma, From the Clinic to the Lab and Back Again

Sharma's novel idea, which ended up being instrumental in advancing checkpoint immunotherapies, was to do what she calls "reverse translation." Sharma begins this process by observing things in the clinic. She then brings these observations back to the lab in order to test new hypotheses needed to further understand how patients respond to cancer immunotherapies and uncover ways to improve them. For example, long before the FDA approved the checkpoint immunotherapy ipilimumab (Yervoy) for melanoma patients, Sharma experimentally treated bladder cancer patients with it before removing their tumors surgically. This enabled her to examine how the tumors responded to the treatment, and if there was a response, to assess what immune components were causing that response. Through this work, Sharma discovered that T cells (a type of immune cell) that expressed a protein called ICOS increased in the tumors of patients responding to ipilimumab, and that this correlated with improved survival of melanoma patients. These findings led Sharma to hypothesize that ICOS was important for effective anti-tumor immune responses to ipilimumab. She then tested this idea in the lab using mouse models and found it to be true. Now a combination therapy of ipilimumab and an experimental agent that acts on ICOS is in clinical testing for use in patients with many different types of cancers, including melanoma.

A similar clinic-to-lab and back again research approach has allowed Sharma to uncover other key players in the anti-tumor immune response and led her to be involved in more than 100 clinical trials at MD Anderson Cancer Center that have enrolled over 4000 patients. "Multiple immune checkpoints exist and are dynamic in their expression and should be evaluated in both pre- and on-treatment human tumor samples to guide therapeutic decisions. We need to understand where and when they play a key role," Sharma said. She also stressed, "Pre-surgical and tissue-based clinical trials provide a feasible platform to study clinical and biologic effects in patients, which provide insights into mechanisms that can be targeted for rational combination therapies." Since receiving her MRA Young Investigator Award in 2008, Sharma has received large grants from the National Cancer Institute, the American Cancer Society, and other major funders.

Dr. Kulkarni, Engineering Better Melanoma Therapies

Ashish Kulkarni also has received major grants from the American Cancer Society and the Cancer Research Institute since receiving his MRA award in 2017. With a background in chemistry and biomedical engineering, he aims to use nanotechnologies to both create new cancer immunotherapies as well as to reveal within days whether these drugs are working. Although just two years into running his own lab, Kulkarni has made substantial progress on both goals thanks to his MRA Young Investigator Award that provided his first funding as an independent investigator. He used sophisticated computer modeling to design a self-assembling nanoparticle compound that latches onto a key receptor jutting out of the surface of macrophages, immune cell that can suppress anti-tumor immunity. The nanoparticles block the receptor, thereby limiting the immunosuppressive functions of the macrophages', allowing them to engulf and digest tumor cells. Thanks to the computer modeling, he was able to design a compound that can be delivered at greater and longer-lasting concentrations to tumor cells without increasing concentrations in healthy tissues, all of which makes it more likely the nanoparticles will be safe and effective in human patients. In a melanoma mouse model, "Just a single dose gave significant antitumor activity," Kulkarni stressed. If he continues to get good results with additional testing, this pioneering approach to designing and developing new drugs has potential to change how drug development is done.

Kulkarni also created nanoparticles that activate an imaging agent, causing telltale fluorescence when there is a response to the PD1-targeted immunotherapy in mice. "It's exciting that it can distinguish in real time between responders and non-responders," Kulkarni said, noting that his probe could be used in MRI imaging if initial promising findings on it are confirmed through further testing.

Going Beyond Funding to Support its Young Investigators

Recognizing that in addition to funding, mentoring is a crucial component to furthering a research scientist's career, a mentorship commitment from a senior investigator is required for all MRA Young Investigator Award applicants. MRA also provides its own form of mentoring by fostering connections and providing career-focused information at its annual Young Investigators

Ashish Kulkarni of University of Massachusetts

Kulkarni's pioneering approach to designing and developing new drugs has potential to change how drug development is done.

Breakfast. These breakfasts have featured editors from top scientific journals providing tips on navigating the publishing process, presentations on how to collaborate productively with colleagues, and information on non-traditional funding sources. In 2020, the Young Investigators Breakfast had a presentation on mentoring by Kelly Diggs-Andrews, a Master Facilitator with the National Research Mentoring Network. "Mentoring is essential and there is a host of research that shows strong mentoring relationships enhance identity, a sense of belonging, and self-efficacy, persistence, research productivity, higher career satisfaction, and enhanced recruitment of women and minorities," she stressed during her presentation.

Beyond its Young Investigator Breakfasts, MRA offers other mentoring and collaboration opportunities at its annual scientific retreats. Sharma, for example, received instrumental input during a previous Scientific Retreat that helped her design better experiments, projects, and compete for more advanced grants. "MRA is a core group who will always help to move the field forward," Sharma said.

Melanoma > Exchange Patient & Advocate Forum

When melanoma comes into your life, your life will never be the same, whether you recognize it as such or not. No one knows this feeling better than other people who've experienced it firsthand. This is why MRA's **Melanoma > Exchange Advocate Forum** is always such a charged, passionate, and powerful experience.

In 2020, the forum brought almost 150 patients, survivors, and loved ones together with world-renowned melanoma clinicians and researchers. In addition, for the first time ever, over 700 registered to join us through the event livestream.

Participants – virtual and those joining us in person – walked away with practical tips and strategies to get the most out of their care while navigating the challenges of melanoma diagnosis, treatment, and beyond.

Videos from the 2020 **Melanoma > Exchange Advocate Forum** are now available at **CureMelanoma.org/Forum**

Expanding the Tool Box:

New Melanoma Treatment Approaches Being Explored

Patient receives infusion of checkpoint immunotherapy

Despite the tremendous progress made in melanoma treatments over the last 10 years, with 2 FDA-approved treatments blossoming to 14 and many metastatic melanoma patients experiencing remissions that are starting to look like cures, only about half of such patients respond favorably to current treatments. No one knows this better than 23-year-old Grace Wenzel, who spoke at the MRA's 2020 Scientific Retreat via a video filmed from her hospital bed. Diagnosed in October, 2018 with Stage 4 melanoma, she had all the innovative treatments so far approved by FDA, including combination immunotherapies, to which she didn't respond, and combination targeted therapies, which quickly shrank her tumors but stopped being effective in May of 2019.

Rizwan Haq of Dana-Farber Cancer Center

The Current Landscape of FDA-Approved Treatments — The Successes & Remaining Hurdles

Why don't the new melanoma treatments provide a lasting benefit for some patients like Grace, and what is being done to improve them? Rizwan Haq, an MRA-funded physician-scientist at Dana-Farber Cancer Institute, broadly addressed both questions as he provided the opening lecture at MRA's Melanoma > Exchange Patient & Advocate Forum.

To set the stage, Dr. Haq outlined the two broad categories of treatment approaches predominantly used in the United States today for patients with advanced melanoma. One approach called 'targeted therapy' turns off the molecular switches that drive melanoma tumor growth. Currently, targeted therapies are only effective in melanoma patients whose tumors have a genetic defect in the protein BRAF. The other treatment approach releases the breaks on the patient's immune system to respond to tumors, and is called 'immune-based therapies' or 'immunotherapy.' Some immunotherapies are given systemically, while others are injected directly into accessible melanoma tumors.

From left: Antoni Ribas, James Moon, Stephanie Goff, Georgia Beasley, Kenneth Grossmann, and Marlana Orloff

Targeted therapies quickly put most patients with BRAF mutant melanoma into remission, but over time cancer usually becomes resistant to targeted treatments by finding other molecular pathways to fuel its growth. So, most patients tend to see their tumors recur within months to years after starting targeted therapies — although about 20% of patients experience durable benefits from combination targeted therapy. Researchers are avidly pursuing multiple strategies to overcome this drug resistance, including simultaneously targeting additional molecular switches for tumor growth, creating more powerful drug inhibitors for existing switches, or giving targeted therapies intermittently rather than continuously. The latter strategy has generated more durable responses in mice and is currently being tested in the clinic, as are clinical trials examining altogether new combinations of these molecularly targeted therapies.

Patient responses generated by immunotherapies tend to be more durable than those from targeted therapies, but a sizable portion of melanoma patients still do not respond to them at all. Researchers are starting to understand why, uncovering that the effectiveness of these therapies appears to depend on specific factors related to the tumor, the patient's immune system, and even microbes in a patient's gut. Some patients' tumors lack the molecular knobs current immunotherapy drugs grab on to kill tumor cells. Other patients' tumors may lack enough T cells in the vicinity of the tumor, or enough foreign particles called antigens made by tumor cells that the immune system uses to recognize and attack. Studies in mice also show that microbes in patients' gut influence response to immunotherapies in ways we are just beginning to understand.

Overcoming Hurdles: The Next Decade of Melanoma Treatments

Picking up where Dr. Haq left off, a panel of world-renowned melanoma experts from across the United States shared how researchers are devising new agents and approaches to overcome the limitations of existing therapies presented by Haq. The panel, moderated by MRA-funded investigator, Dr. Marlana Orloff, featured panelists Dr. Antoni Ribas, Dr. Stephanie Goff, Dr. James Moon, Dr. Kenneth Grossmann, and Dr. Georgia Beasley and highlighted emerging treatment approaches that may help more patients experience better outcomes.

Cancer-Fighting Vaccines

One type of immune-enhancing treatment currently being tested in the clinic is a vaccine injected directly into tumors that can spur an antitumor response even in tumors not treated directly. "It trains the immune system to recognize and attack melanoma no matter where it appears and no matter how much later it appears," says Dr. Antoni Ribas, an MRA-funded physician-scientist from the University of California, Los Angeles. The vaccines being studied are comprised with either viral or bacterial proteins recognized and known to jumpstart the immune response. In some vaccines, these proteins are inserted into viruses that attack cancer cells. James Moon, an MRA-funded investigator from the University of Michigan, reported on another type of tumor vaccine he

is developing in collaboration with the company Evoke to enhance response to current immunotherapies. This "personalized" vaccine is comprised of new antigens produced by patients' tumors that are then combined with immune-stimulating agents. "We're getting exciting results in mice and humans," Moon said, noting that the vaccine is being given to Stage III patients along with existing immunotherapies following surgery in a clinical trial aimed at preventing relapse.

Tumor Infiltrating Lymphocytes

Another personalized approach to treating melanoma is being explored at the National Cancer Institute, Dr. Stephanie Goff reported. There, she and her colleagues are harvesting tumor-attacking T cells from advanced melanoma patients and multiplying them in culture. After giving these patients extensive chemotherapy that temporarily destroys their bone marrow, creating a blank slate for new immune cells, they then inject patients with these cultured tumor-infiltrating T cells. So far, the investigators have treated 40 cancer patients with a response rate of about 40%, even if these patients previously did not respond to any of the approved immunotherapies. "So, something different is going on there. If the first line of drugs doesn't work, these tumor-infiltrating lymphocytes still can, but we're still trying to sort out who are the right patients to treat with it," she said.

James Moon of the University of Michigan and Antoni Ribas of the University of California Los Angeles (UCLA)

"Not all melanomas are created equal."

— Marlana Orloff

Individualized Approaches Driven by Biology

In his framing remarks, Dr. Haq noted that the best choice between available treatment options will likely differ between patients. This highlights the need to understand patients' specific immune responses to tumors and to have diagnostic tests that can elucidate them. Investigations have revealed some promising findings in this regard that could come to the clinic soon. Marlana Orloff, a rare-melanoma specialist from Thomas Jefferson University, also highlighted how diverse melanoma tumors are, even when derived from the same patient. She stressed we have to understand this diversity to make progress with treatments. "Not all melanomas are created equal—even patients with the same size tumors respond differently, and tumors in the brain and liver are more difficult to treat than those found elsewhere," Orloff stressed.

The panelists also stressed that a better understanding of the unique molecular defects that cause or fuel the growth of rare melanoma subtypes that form in the eye, mucous membranes, and on the hands and feet should lead to more effective treatments. "There's much more room for improvement," said Orloff, noting that responses in mucosal melanoma to existing immunotherapies are only half what they are for cutaneous melanomas. Current treatments aren't as effective for rare melanoma subtypes largely because the underlying biology that causes and feeds these melanomas is just so different than that of melanomas that form on sun-exposed skin. Agents targeting some of the specific mutations found in these rare subtypes are currently in clinical trials but are complicated by the wide range of such mutations.

Georgia Beasley of Duke University

Novel Combinations

Perhaps more effectiveness can be achieved by combining immunotherapies with targeted therapies. Researchers are showing encouraging early results by combining PD-1 checkpoint immunotherapy with BRAF/MEK targeted therapies, according to Dr. Grossmann, from the University of Utah Huntsman Cancer Institute. But he noted that the long-term benefits of these approaches are not known yet, and there is an increased possibility of side effects with combination therapy, which might be reduced by giving treatments sequentially rather than simultaneously. A better understanding of what causes side effects can also lead to their amelioration, studies in patients have shown, Grossmann noted.

Moving to Earlier Stages of Disease Through Adjuvant & Neoadjuvant Therapy

Currently, patients with no evidence of disease following surgery to remove melanoma are eligible for adjuvant therapy — or the use of systemic therapy to reduce the likelihood of relapse. Another option, that might be even more effective, is to administer systemic treatment before surgery in early-stage patients at high risk of recurrence. "Treating patients at earlier stages makes sense because there is less cancer there to kill so it's like you are climbing a hill rather than a mountain," said Dr. Georgia Beasley of Duke University. Initial findings suggest that such neoadjuvant treatment can slash the chance of recurrence in half, she reported. By shrinking tumors before surgery, it can also make them easier to remove, with the added benefit that investigators can assess if the treatment given is working by analyzing removed tumor tissue. Risks with this strategy are that cancer could spread during the pre-surgery treatment period and that some patients who receive it will suffer serious side effects of treatment without any additional benefits. "This is an exciting experimental strategy that we're doing with a lot of patients in clinical trials," Beasley said.

Haq concluded his presentation by stressing "Research is the engine that will drive advances and gains in treatment." Orloff added, "Patients often ask why aren't things moving faster and I feel their frustration, but good science takes time and we want to make sure we're doing it right for the patient's sake." These sentiments were echoed by Grace as she ended her remarks, stressing, "Be determined to keep asking and searching. And be determined to keep fighting to find a cure."

"Treating patients at earlier stages makes sense … You are climbing a hill rather than a mountain."

— Georgia Beasley

Leon and Debra Black

Kelly Diggs-Andrews

Shaheen Khan explains her poster to an attendee

Vern Sondak

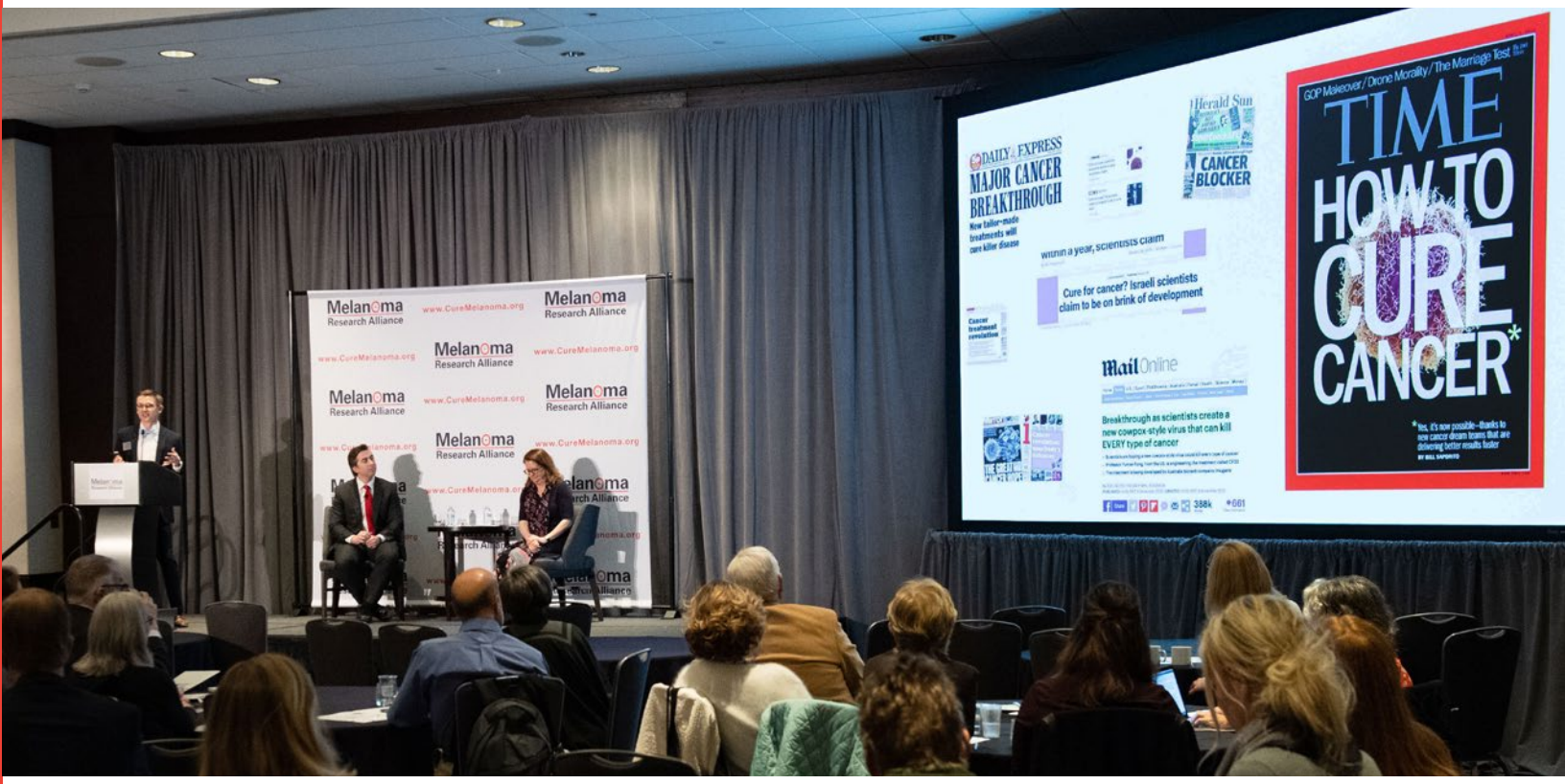
Joann Elmore

Plenary lecture hall

MRA Chief Science Officer Marc Hurlbert

Separating Hope From Hype

Separating Hope From Hype



From left: Cody Barnett, Jason Luke, and Liz Szabo

Melanoma research has undoubtably transformed what it means to be diagnosed with melanoma. For many patients facing melanoma, research has become synonymous with hope, and for good reason. In the last decade alone 12 therapeutic approaches have earned FDA approval giving patients, families, and clinicians new tools to treat melanoma. Up from 5-10% of patients in 2007, today about half of patients with advanced disease respond to available treatments; some may even be cured.

But there can be a fine line between hope and hype, especially today when news — both true and inflated — travels instantly via the internet and social media. As MRA President and CEO Michael Kaplan stressed in his opening remarks at the 2020 Melanoma > Exchange Patient & Advocate Forum, "Patients and their advocates need to understand what is real science now and what is just hot air." To help in this regard, the MRA brought together oncologist Jason Luke of the University of Pittsburgh and medical journalist Liz Szabo of Kaiser Health News for an informative — and grounding — discussion on how to separate

"Patients and their advocates need to understand what is real science now and what is just hot air."

— MRA President and CEO Michael Kaplan

hype from hope, and the problems that can arise when the fine line separating the two is overstepped.

"There are real consequences to giving people false hope and inappropriate expectations that affects their care, comfort, and decisions about how they want to spend the rest of their lives," noted Szabo. This is especially true in melanoma where the differences between patients who do exceptionally well and those who get little or no benefit from available treatment approaches is still poorly understood. Luke added, "Hope is good, but hype can be a barrier to reasonable expectations."

Jason Luke of University of Pittsburgh

"Hope is good, but hype can be a barrier to reasonable expectations."

— Jason Luke

Hype can be fueled at almost all levels, by scientists who need to out-compete others for grant funding to continue their work, by universities who want to highlight important work done on their campus, by government officials who want to herald the next great thing, pharmaceutical companies who have to please shareholders and hit sales targets, and journalists that "play the role of cheerleader because it gets them on the front page of a newspaper or on the 6 'o clock news," Szabo noted. "Almost everyone has some motivation to hype," she said, including patients and their families.

To separate hope from hype, Szabo suggested paying attention to the source of information about a new treatment, and relying more on reputable sources such as the American Cancer Society, the National Cancer Institute, the Food and Drug Administration, and the Melanoma Research Alliance. "Joe's cancer blog is not where I would go for information," Szabo said. She also stressed that "Misinformation spreads faster than the coronavirus. If it seems too good to be true then it probably is. A red flag for snake oil is a treatment that supposedly works for every kind of disease because that is never true."

Szabo also cautioned against being seduced by articles that only highlight one patient who is doing amazingly well on an experimental treatment. "You need to know the denominator—is this one out of two people who do great on the treatment or only one out of 1000?" she said.

Dr. Luke added that because President Jimmy Carter did so well on his immunotherapy for melanoma, people assumed that everyone would.

Unfortunately, the sobering reality is that while more patients are responding than ever before, the majority of patients with late stage melanoma are unlikely to respond as well as President Carter.

Szabo noted that even when a clinical trial is generating positive results, these results may not apply perfectly to the general population because older and sicker people are historically excluded from participating in clinical research. Although eligibility criteria for clinical trials has slowly evolved towards being more inclusive of patients with diabetes, heart disease or other health conditions besides cancer, or those with metastases in their brain — these patients have historically not been included in clinical studies. "You don't want to say no to progress, but you need to be realistic," she stressed.

Luke pointed out that scientific progress tends to be slow, sometimes taking close to a decade from the time an experimental agent shows initial promise in the laboratory to the time it can be used in patients. He suggested that "if you read an article showing results only in animals and you can't figure out how it would change what you would do now, then it probably can't.

We're excited about the treatments we may have in the future, but these are not options we can grab and use now. We need to focus on what we can do here and now."

The good news for patients and families who are navigating the surge in information focused on promising research is that they aren't facing this alone. Luke recommended that patients work together with their doctors and care team to assess any information about new treatment approaches or emerging research to put it into the context of their current treatment plan. What is hyped today may be discarded tomorrow when more results come in, both Luke and Szabo stressed. "Just because it's new doesn't mean it will be better," Szabo noted, pointing out that for every successful new drug, there may be a thousand experimental drugs that fail.

That being said, both Luke and Szabo suggested patients consider participating in a clinical trial if that appears to be their best treatment option, and they have the resources and the energy to do so. But patients and their families should also ask questions to understand the additional hassles — such as extra tests, visits to the doctor, etc. — and how likely these may work for them. A clinical trial may require patients to travel out of their area for treatment or to reside for long periods of time away from home, with no guarantee that the experimental therapy will work. "They can go the clinical trial route, but the reason a treatment is in a research trial is because we haven't proven anything yet," Luke noted.

Luke tries to be forthright in his discussions with patients about clinical trials. "I first tell them why a clinical trial will be horrible before I tell them why I am excited about it," he said. "Expectation management is very important." Szabo agreed, saying "You don't want to give [patients] false hope that makes them disappointed and creates a lost opportunity to have end-of-life conversations."

Part of that false hope can stem from poor communication between doctors and patients or incorrect assumptions

Liz Szabo of Kaiser Health News

"If it seems too good to be true then it probably is."

— Liz Szabo

about what words like 'respond' mean in the context of cancer care. "If your doctor tells you your tumor is likely to respond to a treatment, that doesn't mean it will be cured by the treatment," Szabo noted.

For example, in one study of patients with advanced lung or colorectal cancer researchers found that most of the participants mistakenly thought the chemotherapy they were being given solely to help relieve their symptoms — what doctors call palliative care — was going to cure them of their cancer. She also gave the example of a good friend of hers who died in the ICU from metastatic breast cancer because she continued taking a treatment that was unlikely to work and made her very sick. "If you only have weeks left, you may not want to travel to a hospital but instead travel to see a mountain or that brother you haven't seen in years," she said, adding, "I've lost dear friends to cancers so it makes me committed to not hyping cancer treatments." ⊙

Agendas

Melanoma Research Alliance

MRA 2020 Scientific Retreat

February 26 – February 28, 2020, Washington, DC

Wednesday, February 26

7:30am- 5:00pm	Grant Review Committee Meeting (by invitation) ..... Salon I
12:00-5:30pm	Melanoma Patients, Advocates & Foundations Forum ..... Salon IV
4:00-8:00pm	*Retreat Registration open ..... Foyer of Penn Avenue Terrace*
6:00-7:30pm	**Opening Reception ..... Penn Avenue Terrace**

Thursday, February 27

6:30am-6:00pm	Registration ..... Foyer of Salon III & IV
7:00-8:15am	General Breakfast ..... Salon II
7:00-8:15 am	Young Investigators Breakfast (by invitation) ..... Salon I
8:30-8:45am	**Opening Remarks Day 1 ..... Salon III & IV** Michael Kaplan, MRA President & CEO Marc Hurlbert, MRA Chief Science Officer Grace Wenzel, Patient Advocate
8:45-9:15am	**Lecture** **Jedd Wolchok, Memorial Sloan Kettering Cancer Center:** Maintaining innovation: New directions in melanoma research
9:15-11:25am	**Session 1: Novel therapeutic approaches for treating melanoma** ***Chair: Ronit Satchi-Fainaro, Tel-Aviv University***
9:15-9:40	**Thorsten Mempel, Massachusetts General Hospital:** CARMA1 in control of regulatory T cell function in melanoma
9:40-10:05	**Elaine Fuchs, The Rockefeller University:** How skin stem cell biology can guide us to the basis for tumor relapse
10:05-10:20	*Break*
10:20-10:40	**Nick Huntington, Monash University:** Therapeutic modulation of natural killer cell response to growth factors in melanoma
10:40-11:00	**Rizwan Haq, Dana-Farber Cancer Institute:** Melanoma selective cytotoxicity achieved through a novel switchable kinase inhibitor
11:00-11:25	**Richard White, Memorial Sloan Kettering Cancer Center:** Why tumors appear where they do: positional memory in the pathogenesis of acral melanoma
11:25-11:55am	**Lecture: Padmanee Sharma, University of Texas MD Anderson Cancer Center:** From the clinic to the lab: Investigating response and resistance mechanisms to immune checkpoint therapy

11:55am-12:05pm *Transition to lunch*

12:05-1:05pm **Networking Lunch and General Roundtables #1.....Salon I & II**

Seating at roundtables limited by prior registration. Additional tables with open seating available for general networking and/or scheduled meetings. Topics are:

1. Acral melanoma;
2. AI/imaging/diagnostics;
3. Brain metastasis and leptomeningeal;
4. Cell therapy (ACT, TIL, etc);
5. Clinical trials: multi-site and patient recruitment;
6. Founding your own company;
7. IO-understanding immune-related adverse events;
8. Microbiome;
9. MRA dermatology fellows;
10. Neoadjuvant and adjuvant treatments;
11. Overcoming resistance to IO/targeted therapies;
12. Pediatric and young adult melanoma;
13. Predictive, diagnostic & prognostic biomarkers;
14. Prevention & early detection;
15. Role of genetics, genomics, & epigenomics;
16. Single-cell technologies sequencing and imaging;
17. Targets: finding/validating new targets & drug discovery;
18. Treatment: combos, sequencing, and duration of treatment;
19. Tumor microenvironment;
20. Vaccines & intralesional therapies.

12:00-2:00pm Scientific Advisory Panel meeting and lunch (by invitation).....The Senate Room

1:05-1:20pm *Transition to general session room (Salon III & IV)*

1:20-2:30pm **Session 2: Understanding melanoma metastasis**
Chair: Ashani Weeraratna, Johns Hopkins University

1:20-1:45 **Eva Hernando, New York University:** Melanoma-secreted Amyloid Beta Suppresses Neuroinflammation and Promotes Brain Metastasis

1:45-2:05 **Florian Karreth, Moffitt Cancer Center:** MicroRNA deregulation in melanoma progression

2:05-2:30 **Carmit Levy, Tel Aviv University:** Identification of novel regulators of melanoma brain metastasis

2:30-2:50pm *Break*

2:50-4:00pm **Session 3: Special Focus — Acral Melanoma**
Chair: Nick Hayward, QIMR Berghofer Medical Research Institute

2:50-3:15 **Boris Bastian, University of California, San Francisco:** The genetics of acral melanoma

3:15-3:35 **Phyu Aung, University of Texas MD Anderson Cancer Center:** Acral melanoma – histologic and molecular studies

3:35-4:00 **Ruth Halaban, Yale University and Aaron Newman, Stanford University:** Recurrent patterns of structural variation promote tumorigenesis in acral melanoma

4:00-4:30pm **Lecture: James Allison, University of Texas MD Anderson Cancer Center:** Immune checkpoint blockade in cancer therapy: Historical perspective, new opportunities, and prospects for cures

4:30-4:35 **Closing Remarks Day 1**
Kristen Mueller, MRA Senior Director, Scientific Program

4:45-6:15pm **Young Investigator, Dermatology Fellow, and Pilot Awardee Poster Session.....Penn Avenue Terrace**
All retreat attendees encouraged to attend

4:45-5:45pm ACS-MRA grant awardees reception (by invitation).....State Room

6:30-9:00 pm **Reception and Dinner** ..... **Zaytinya,** 701 9th St NW
Dress: Casual
Reception: 6:30-7:00pm; Dinner 7:15pm

Friday, February 28

6:30-10:00am *Registration open* ..... *Foyer of Salon III & IV*

7:00-8:30am **Networking Breakfast and General Roundtables #2** ..... **Salon I & II**

Seating at roundtables limited by prior registration. Additional tables with open seating available for general networking and/or scheduled meetings. Topics are:

1. Clinical trials: Benefits and impediments to Phase 1 trials;
2. Founding your own company;
3. Sex-related biology and melanoma;
4. Heterogeniety and phenotype switching
5. IO – understanding immune-related adverse events;
6. Melanoma metastases – dormancy;
7. Overcoming resistance to IO/targeted therapies;
8. Predictive, diagnostic & prognostic biomarkers;
9. Prevention & early detection – melanoma initiation;
10. Role of genetics, genomics & epigenomics in melanoma;
11. Surgery: current and emerging methods of surgical treatment;
12. Targets: finding/validating new targets & drug discovery;
13. Tumor metabolism and metabolomics;
14. Tumor microenvironment;
15. Understanding the biology of in-transit melanoma;
16. Uveal & mucosal melanoma;
17. Women in melanoma research & care.

7:00-8:30 am Industry Roundtable Breakfast (by invitation) ..... Salon FG

8:40-8:45 am **Opening Remarks Day 2** ..... **Salon III & IV**
Kristen Mueller

8:45-9:15am **Lecture: Christian Blank, Netherlands Cancer Institute:**
Neoadjuvant approaches for treating melanoma

9:15-10:25am **Session 4: Understanding melanoma initiation to improve patient outcomes**
Chair: Sheri Holmen, Huntsman Cancer Institute at University of Utah

9:15-9:35 **Eleonora Leucci, Katholieke Universiteit Leuven:** LncRNAs as modulators of protein synthesis rewiring in melanoma

9:35-10:00 **Lorenz Studer, Memorial Sloan Kettering Cancer Center:** Cell of origin as a driver of heterogeneity in melanoma

10:00-10:45 *Break*

10:45-11:30am **Session 5: Novel approaches for diagnosing melanoma and assessing therapeutic efficacy**
Chair: Christin Burd, Ohio State University

10:45-11:05 **Ashish Kulkarni, University of Massachusetts, Amherst:** Nanoscale Approaches for Targeting Tumor-associated Macrophages

11:05-11:30 **Joann Elmore, University of California, Los Angeles:** The importance of applying AI to assess histologic features to improve melanoma diagnosis

11:30am-12:15pm **Panel Discussion: Maintaining the momentum:** New directions in melanoma research
Moderator: Michael Atkins, Georgetown University, Chair of MRA Medical Advisory Panel

- Susan Swetter, Stanford University
- Suzanne Topalian, Johns Hopkins University, Chair of MRA Scientific Advisory Panel, MRA Board of Directors
- Richard Carvajal, Columbia University

- Marisol Soengas, Spanish National Cancer Research Center
- Lorenzo Cohen, University of Texas MD Anderson Cancer Center

12:15pm-12:30pm **Closing Remarks**
Michael Kaplan and Marc Hurlbert

12:30-1:30pm **Lunch and Departures .....Salon II**

12:30-6:00 pm **Lunch and Melanoma Models Workshop** (Chaired by Dr. Liz Patton and Dr. Glenn Merlino) (by invitation) .....**Salon I**

Melanoma > Exchange
Patient & Advocate Forum February 26, 2020

12:00-1:00pm **Lunch & Networking**

1:00-1:10pm **Welcome Remarks**
Michael Kaplan – President & CEO, Melanoma Research Alliance

1:10-1:30pm **Who We Are & Why We Are Here**

1:30-2:20pm **The Melanoma Treatment Landscape**
Learn where we are, where we've been, and where research is taking us.
Rizwan Haq, PhD, MD – Dana-Farber Cancer Institute

2:20-2:30pm *Break*

2:30-3:30pm **Is it Hope or Hype?**
We've all see headlines proclaiming the imminent cure for cancer, only to be let down after reading just a few lines. Learn how to separate hype from hope.
Jason Luke, MD – University of Pittsburgh
Liz Szabo – Kaiser Health News

3:30-4:00pm **Ask the Expert: Animal Models**
What role do animal models play in developing next-generation melanoma therapies?
Liz Patton, PhD – University of Edinburgh

4:00-4:15pm *Break*

4:15-5:45pm **Looking Beyond 2020 – The Next Decade of Melanoma Treatment**
The melanoma treatment landscape has more options than ever. Hear from experts on emerging approaches gaining steam in clinical trials and the clinic.
Georgia Beasley, MD – Duke University
Stephanie Goff, MD – National Cancer Institute
Kenneth Grossman, MD, PhD – University of Utah
James Moon, PhD – University of Michigan
Antoni Ribas, MD, PhD – University of California Los Angeles
Moderator: *Marlana Orloff, MD – Thomas Jefferson University*

5:45-6:00pm **Closing & Wrap-up**

6:00-7:30pm **MRA Patient, Advocate, & Researcher Reception**

Keep the conversation going on the **Melanoma > Exchange** online discussion community.
CureMelanoma.org/Community

Participants

Dave Adams
Wellcome Sanger Institute
da1@sanger.ac.uk

Rhoda Alani
Professor and Chair
Boston University School of Medicine
alani@bu.edu

Kimberly Albertson
Patient Advocate
berlybabsmichael1@icloud.com

James Allison
Chairman, Department of Immunology;
UT MD Anderson Cancer Center
jallison@mdanderson.org

Niroshana Anandasabapathy
Associate Professor of Dermatology,
Attending Physician
Weill Cornell Medicine
niroananda@gmail.com

Ana Anderson
Associate Professor
Harvard Medical School
aanderson@rics.bwh.harvard.edu

Margaret Anderson
Board of Directors
Melanoma Research Alliance

Andrew Aplin
Associate Director
Thomas Jefferson University
andrew.aplin@jefferson.edu

Frederic Appelmans
Global Marketing Director
Amgen
fappelma@amgen.com

Victoria Aranda
Senior Editor
Nature
v.aranda@us.nature.com

Charlotte Ariyan
Attending
Memorial Sloan Kettering Cancer Center
ariyanc@mskcc.org

Maryam Asgari
Associate Professor
Massachusetts General Hospital
masgari@partners.org

Michael Atkins
Deputy Director
Georgetown University
mba41@georgetown.edu

Phyu Aung
Associate Professor
UT MD Anderson Cancer Center
paung@mdanderson.org

Michael Axelson
Head of Clinical Research
Tempus
michael.axelson@tempus.com

Shirin Bajaj
Resident Physician
NYU Langone Medical Center
shirin.bajaj@nyulangone.org

Anand Balasubramani
Associate Editor
Science Immunology
abalasubramani@aaas.org

Riyue Bao
Co-Director of Cancer Bioinformatics
UPMC Hillman Cancer Center
baor@upmc.edu

Boris Bastian
Professor
UCSF
boris.bastian@ucsf.edu

Kristina Baum
Communications Director
White House Office of Science and
Technology Policy
baum.kristina@gmail.com

Georgia Beasley
Assistant Professor of Surgery, co-director
Duke Cancer Institute Melanoma Program
georgia.beasley@duke.edu

Barbara Bedogni
Associate Professor
University of Miami
bxb602@miami.edu

Valerie Behan
Scientific Program Manager
Rising Tide
valerie.behan@risingtide.ch

Emily Bernstein
Professor
Icahn School of Medicine at Mount Sinai
emily.bernstein@mssm.edu

Corine Bertolotto
INSERM
Corine.Bertolotto@unice.fr

Ben Black
Board of Directors
Melanoma Research Alliance

Debra Black
Co-Founder and Chair
Melanoma Research Alliance

Leon Black
Co-Founder
Melanoma Research Alliance

Christian Blank
Professor, Group Leader
Netherlands Cancer Institute
c.blank@nki.nl

Kim Blenman
Associate Research Scientist
Yale University
kim.blenman@yale.edu

Gideon Bollag
CEO
Plexxikon
gbollag@plexxikon.com

President and CEO Michael Kaplan

Jean Bolognia
Professor
Yale University
jean.bolognia@yale.edu

Marcus Bosenberg
Professor of Dermatology, Pathology, Immunobiology
Yale University
marcus.bosenberg@yale.edu

Jay Braxton
Executive Director, Medical Affairs
Castle Biosciences, Inc.
jbraxton@castlebiosciences.com

Tripp Brockway
Patient Advocate
dhbrockway@gmail.com

Peter Bross
Oncology Team Lead
US Food & Drug Administration
peter.bross@fda.hhs.gov

Norm Brownstein
Chairman
Brownstein Hyatt Farber Schreck, LLP

Timothy Bullock
Associate Professor
University of Virginia
tb5v@virginia.edu

Christin Burd
Assistant Professor
The Ohio State University
burd.25@osu.edu

Karen Burke
Dermatologist
kebmdphd@gmail.com

Matthew Burke
Associate Director, US I/O Medical Scientist
Bristol-Myers Squibb
matthew.burke@bms.com

Robyn Burns
Science Officer
Melanoma Research Foundation
Rburns@melanoma.org

Tal Burstyn-Cohen
Principal Investigator
Hebrew University
talbu@ekmd.huji.ac.il

Katherine Byrnes
Executive Director
Skin of Steel
katherinebyrnes@sbcglobal.net

Tracy Callahan
CEO, Founder
Polka Dot Mama Melanoma Foundation
polkadotmamainc@gmail.com

Richard Carvajal
Associate Attending Physician
Columbia University Irving Medical Center
rdc2150@cumc.columbia.edu

M. Graciela Cascio
Postdoctoral Fellow
Weill Cornell Medicine
mgc2002@med.cornell.edu

Craig Ceol
Assistant Professor
University of Massachusetts Medical School
Craig.Ceol@umassmed.edu

Paul Chapman
Attending Physician
Memorial Sloan Kettering Cancer Center
chapmanp@mskcc.org

Herman Chavez
Miggy's Gift, Inc.
miggysgift@gmail.com

Marilu Chavez
Vice President
Miggy's Gift, Inc.
miggysgift@gmail.com

Helen Chen
Physician and Senior Investigator
National Cancer Institute
helen.chen@nih.gov

Suephy Chen
Professor and Vice Chair
Emory University
schen2@emory.edu

Xu Chen
Assistant Professor
UCSF
xu.chen@ucsf.edu

Yiwen Chen
Assistant Professor
UT MD Anderson Cancer Center
ychen26@mdanderson.org

Ping-Chih Chi
Associate Member
Memorial Sloan Kettering Cancer Center
chip@mskcc.org

Jerry Edward Chipuk
Associate Professor & Associate Director of TCI
Icahn School of Medicine at Mount Sinai
jerry.chipuk@mssm.edu

David Cohan
Senior Medical Director
Alkermes
david.cohan@alkermes.com

Lara Porzak

Lorenzo Cohen
Professor
UT MD Anderson Cancer Center
lcohen@mdanderson.org

Hilary Coller
Professor
UCLA
hcoller@ucla.edu

Clara Curiel
Professor
University of Arizona
ccuriel@email.arizona.edu

Sue Currie
Head of Medical Affairs
Nektar Therapeutics
scurrie@nektar.com

Elvan Daniels
Sr Scientific Dir. Cancer Control and Prevention
American Cancer Society
ellie.daniels@cancer.org

Virna Dapic
Sr. Regional Medical Liaison
Amgen
vdapic@amgen.com

Michael Davies
Professor and Chair
UT MD Anderson Cancer Center
mdavies@mdanderson.org

Teresa Davoli
Assistant Professor
NYU Langone Medical Center
teresa.davoli@nyulangone.org

Tanja de Gruijl
Professor
Cancer Center Amsterdam
td.degruijl@vumc.nl

Jean Paul De La O
Medical Science Liaison
Myriad Genetics
jdelao@myriad.com

Titia de Lange
Leon Hess Professor
The Rockefeller University
delange@mail.rockefeller.edu

Daniela De Zio
Senior Scientist
Kraeftens Bekaempelse
dzio@cancer.dk

Steven Deitcher
President, CEO & Board Member
Radimmune Therapeutics
srdeitcher@radimmune.com

Adi Diab
Associate Professor
UT MD Anderson Cancer Center
adiab@mdanderson.org

Scott Diede
Executive Director
Merck & Co.
scott.diede@merck.com

John D'Orazio
Professor of Pediatrics
University of Kentucky
jdorazio@uky.edu

Elizabeth Dorn
Medical Director, Medical Affairs
Alkermes
elizabeth.dorn@alkermes.com

Michael Dougan
Director of the Immunotherapy Mucosal Inflammation Program
Massachusetts General Hospital
mldougan@partners.org

Stephanie Dougan
Assistant Professor
Dana-Farber Cancer Institute
stephanie_dougan@dfci.harvard.edu

Andrew Dudley
Associate Professor
University of Virginia
acd2g@virginia.edu

Reinhard Dummer
Vice-Chairman
University Hospital Zurich
reinhard.dummer@usz.ch

Shelley Earp
Director
The University of North Carolina at Chapel Hill
shelton_earp@med.unc.edu

Joann Elmore
Professor
UCLA
jelmore@mednet.ucla.edu

Mark Faries
Co-Director, Cutaneous Oncology
The Angeles Clinic and Research Institute
mfaries@theangelesclinic.org

Lola Fashoyin-Aje
Deputy Division Director
US Food & Drug Administration
Lola.Fashoyin-Aje@FDA.HHS.Gov

David Fisher
Chief of Dermatology
Massachusetts General Hospital
dfisher3@partners.org

Keith Flaherty
Director of Clinical Research, Cancer Center
Massachusetts General Hospital
kflaherty@mgh.harvard.edu

Greg Friberg
Vice President Global Development
Amgen
gfriberg@amgen.com

Dean Frohlich
Scientific Review Officer
Conquer Cancer Foundation
dean.frohlich@conquer.org

Elaine Fuchs
Investigator, Rebecca C. Lancefield Professor
HHMI, The Rockefeller University
fuchslb@rockefeller.edu

Gina Fusaro
Development Team Lead
Bristol-Myers Squibb
gfusaro@celgene.com

Thomas Gajewski
Professor
University of Chicago
tgajewsk@medicine.bsd.uchicago.edu

Christine Garrison
President
The White Aisle Foundation
thewhiteaisle@comcast.net

Eduard Gasal
Global Program Clinical Development Head
Novartis Pharmaceuticals
eduard.gasal@novartis.com

Evris Gavathiotis
Professor
Albert Einstein College of Medicine
evripidis.gavathiotis@einstein.yu.edu

Tamar Geiger
Principal Investigator
Tel Aviv University
geiger@post.tau.ac.il

Lincy George
Global Therapeutic area Lead - Regulatory Affairs
Novartis Pharmaceuticals
lincy.george@novartis.com

David Gerber
Professor
UT Southwestern Medical Center
david.gerber@utsouthwestern.edu

Jeffrey Gershenwald
Professor
UT MD Anderson Cancer Center
jgershen@mdanderson.org

Michael Goldberg
CEO
STIMIT
michael@stimittx.com

Foster Gonsalves
Vice President, Drug Development & Strategy
Rgenix Inc.
foster.gonsalves@rgenix.com

Mark Gorman
Patient Advocate
mgormanss@mac.com

Nancy Gough
Consultant
BioSerendipity, LLC
ngough@bioserendipity.com

Susanna Greer
Director, Clinical Cancer Research and Immunology
American Cancer Society
Susanna.Greer@cancer.org

Skip Grinberg
Patient Advocate
Meyergrinberg@gmail.com

Kenneth Grossmann
Associate Professor
Huntsman Cancer Institute
kenneth.grossmann@hci.utah.edu

Samantha Guild
Executive Director
AIM at Melanoma
sguild@aimatmelanoma.org

Ray Gustin
Partner
Drake Capital
ray.gustin4@gmail.com

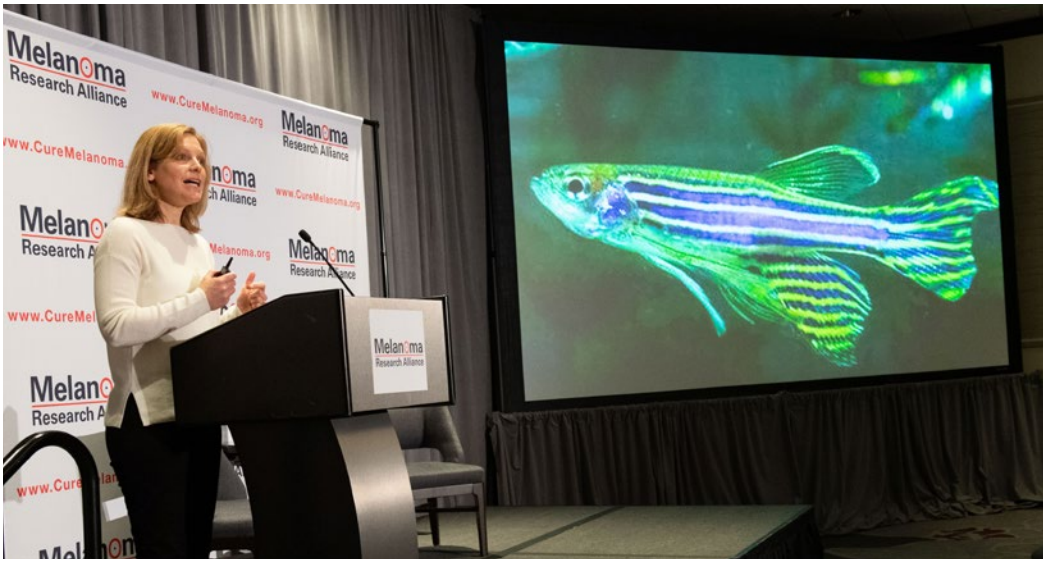
Ruth Halaban
Senior Research Scientist
Yale University
ruth.halaban@yale.edu

Allan Halpern
Chief, Dermatology Services
Memorial Sloan Kettering Cancer Center
halperna@mskcc.org

Omid Hamid
Dir, Melanoma Oncology; Chief, Clinical Research
The Angeles Clinic and Research Institute
ohamid@theangelesclinic.org

Brent Hanks
William Dalton Family Assistant Professor of Medical Oncology
Duke University
hanks004@mc.duke.edu

Rizwan Haq
Assistant Professor
Dana-Farber Cancer Institute
rizwan_haq@dfci.harvard.edu



Liz Patton of University of Edinburgh

J. William Harbour
Professor and Vice Chairman
University of Miami
harbour@med.miami.edu

Christine Harhaj
Director
PhRMA
charhaj@phrma.org

Nicholas Hayward
Senior Scientist
QIMR Berghofer Medical Research Institute
nicholas.hayward@qimrberghofer.edu.au

Maitreyee Hazarika
Senior Medical Officer
US Food & Drug Administration
maitreyee.hazarika@fda.hhs.gov

Simon Heidegger
Senior Scientist
Klinikum rechts der Isar, Technical University Munich
simon.heidegger@tum.de

Daisy Helman
Board of Directors
Melanoma Research Alliance

Shawn Helms
President & CEO
Helms Hope Foundation
shawn@helmshope.org

Meenhard Herlyn
Professor and Program Director
The Wistar Institute
herlynm@wistar.org

Victoria Aranda of Nature Publishing Group

Eva Hernando
Associate Professor
New York University School of Medicine
Eva.Hernando-Monge@nyulangone.org

Jack Hidary
Radimmune Therapeutics
jack@hidary.com

Shannon Hines
Staff Director, Appropriations Committee
U.S. Senate
Shannon_Hines@appro.senate.gov

Frank Stephen Hodi
Director, Melanoma Disease Center &
Center for Immuno-Oncology
Dana-Farber Cancer Institute
stephen_hodi@dfci.harvard.edu

Sheri Holmen
Professor
University of Utah
sheri.holmen@hci.utah.edu

Dave Hoon
Professor Director
John Wayne Cancer Institute
hoond@jwci.org

Thomas Hornyak
Associate Chief of Staff for Research & Development
VA Maryland Health Care System/Univ. of Maryland
thomas.hornyak@va.gov

Timothy Hsiao
Director of Scientific Affairs
ASTRO
timothy.hsiao@astro.org

Ku-Lung Hsu
Assistant Professor of Chemistry and Pharmacology
University of Virginia
kenhsu@virginia.edu

Leah Hubbard
Program Director
National Cancer Institute
leah.hubbard@nih.gov

Willy Hugo
Assistant Adjunct Professor
UCLA
hwilly@mednet.ucla.edu

Siwen Hu-Lieskovan
Assistant Professor of Medicine, Director of Solid Tumor Immunotherapy
Huntsman Cancer Institute
siwen.hu-lieskovan@hci.utah.edu

Nick Huntington
Immunotherapy Head
Monash University
huntington@wehi.edu.au

Marc Hurlbert
Chief Science Officer
Melanoma Research Alliance
mhurlbert@curemelanoma.org

Adam Hurlstone
Senior Lecturer
University of Manchester
adam.hurlstone@manchester.ac.uk

Patrick Hwu
Head, Division of Cancer Medicine
UT MD Anderson Cancer Center
phwu@mdanderson.org

Kimberly Irvine
Patient Insight & Advocacy Officer
OncoSec Medical
kirvine@oncosec.com

Rubina Ismail
Medical Director
Amgen
rismail@amgen.com

Fumito Ito
Associate Professor of Surgery
Roswell Park Cancer Institute
fumito.ito@roswellpark.org

Burkhard Jansen
Chief Medical Officer
DermTech
bjansen@dermtech.com

Russell Jenkins
Assistant Professor
Massachusetts General Hospital
rwjenkins@partners.org

Prakash Jha
Medical Officer
US Food & Drug Administration
Prakash.Jha@fda.hhs.gov

Lucia Jilaveanu
Associate Professor
Yale University
lucia.jilaveanu@yale.edu

Sabrina Joseph
Senior Scientific Program Officer
ASTRO
sabrina.joseph@astro.org

Nikhil Joshi
Assistant Professor
Yale University
nikhil.joshi@yale.edu

Mizuho Kalabis
Oncology Clinical Director
Merck & Co.
mizuho.kalabis@merck.com

Michael Kaplan
President & CEO
Melanoma Research Alliance
mkaplan@curemelanoma.org

Florian Karreth
Assistant Member
H. Lee Moffitt Cancer Center
florian.karreth@moffitt.org

Charles Kaufman
Assistant Professor
Washington University in Saint Louis
ckkaufman@wustl.edu

Howard Kaufman
Replimune
howard.kaufman@replimune.com

Alissa Keegan
Senior Medical Scientist
Amgen
akeega01@amgen.com

Denise Kellen
Board of Directors
Melanoma Research Alliance

Priscilla Kelly
Editor
SCIENCE
pkelly@aaas.org

Shaheen Khan
Assistant Professor
UT Southwestern Medical Center
shaheen.khan@utsouthwestern.edu

Vernon Sondak of Moffitt Cancer Center, Tampa FL and Iwei Yeh of University of California, San Francisco

Nikhil Khushalani
Vice Chair and Senior Member, Cutaneous Oncology
H. Lee Moffitt Cancer Center
Nikhil.Khushalani@moffitt.org

Donna Kimbark
Program Manager
CDMRP-Melanoma Research Program
donna.m.kimbark.civ@mail.mil

Enko Kiprilov
Senior Medical Director
Pfizer
Enko.Kiprilov@arraybiopharma.com

John Kirkwood
Usher Professor of Medicine, Dermatology, and Translational Science
UPMC Hillman Cancer Center
kirkwoodjm@upmc.edu

Libby Kistler
Patient Advocate
opkva117@gmail.com

Michael Klowden
CEO
Milken Institute

Sebastian Kobold
Attending Physician, Professor
Klinikum der Ludwig-Maximilians-Universität München
sebastian.kobold@med.uni-muenchen.de

Larissa Korde
Head, Breast Cancer and Melanoma Therapeutics, Clinical Investigations Branch,
National Cancer Institute
larissa.korde@nih.gov

Clemens Krepler
Clinical Director
Merck & Co.
clemens.krepler@merck.com

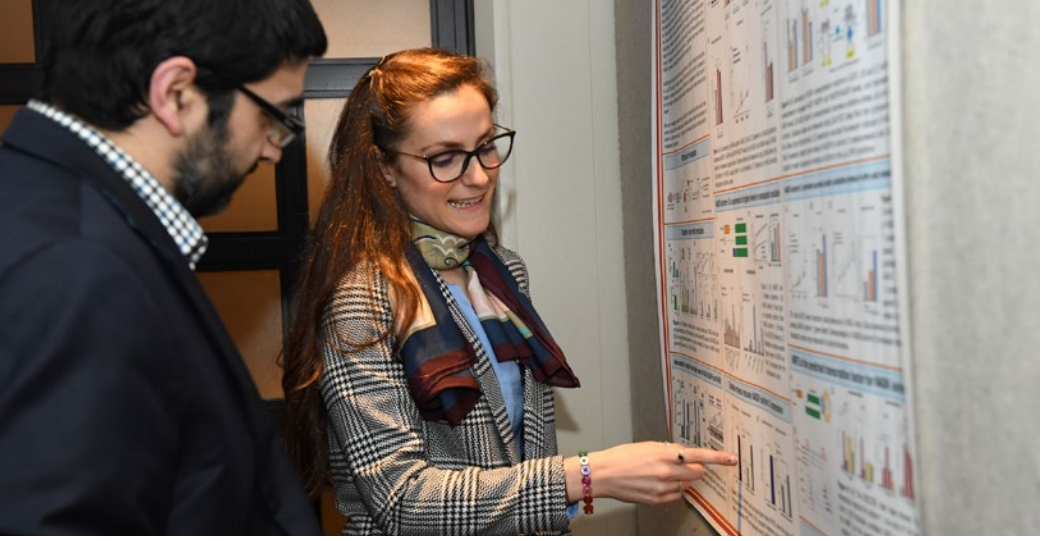
Art Krieg
Chief Scientific Officer & Founder
Checkmate Pharmaceuticals
akrieg@checkmatepharma.com

Esther Krofah
Senior Director
FasterCures, a Center of the Milken Institute
ekrofah@milkeninstitute.org

Ashish Kulkarni
Assistant Professor
University of Massachusetts Amherst
akulkarni@engin.umass.edu

Rajan Kulkarni
Assistant Professor
Oregon Health & Science University
kulkarnr@ohsu.edu

Ann Kurowski
Vice President, Regulatory Affairs
Alkermes
ann.kurowski@alkermes.com



Young Investigator, Pilot, and Dermatology Fellow Awardee Poster Session

Benjamin Larimer
Assistant Professor
University of Alabama Birmingham
blarimer@uab.edu

Theresa LaVallee
VP, Translational Medicine and Reg. Affairs
Parker Institute for Cancer Immunotherapy
tlavallee@parkerici.org

Sancy Leachman
Professor & Chair, Department of Dermatology
Oregon Health & Science University
leachmas@ohsu.edu

Steven Lemery
Division Director, DO3
US Food & Drug Administration
steven.lemery@fda.hhs.gov

Eleonora Leucci
PI and head of Trace
KU Leuven
eleonora.leucci@kuleuven.be

Carmit Levy
Professor
Tel Aviv University
carmitlevy@post.tau.ac.il

Chengyu Liang
Associate Professor
University of Southern California
chengyu.liang@med.usc.edu

Kyleigh Lipra
CEO
Melanoma Research Foundation
klipira@melanoma.org

Evan Lipson
Associate Professor, Medical Oncology
Johns Hopkins University
elipson2@jhmi.edu

Sixue Liu
Postdoctoral fellow
UCLA
sxliu0130@gmail.com

Roger Lo
Professor, Associate Chief, Program Director
UCLA
rlo@mednet.ucla.edu

John Loffredo
Associate Director, Clinical Biomarker Lead
Bristol-Myers Squibb
joh.loffredo@bms.com

David Lombard
Associate Professor of Pathology
University of Michigan
davidlom@umich.edu

Buddy Long
CEO
Elios Therapeutics
buddy.long@perseuspci.com

Michal Lotem
Head, Center for Melanoma and Cancer Immunotherapy
Hadassah University Hospital
mlotem@hadassah.org.il

Jason Luke
Associate Professor of Medicine
UPMC Hillman Cancer Center
lukejj@upmc.edu

Amanda Lund
Associate Professor
Oregon Health & Science University
lunda@ohsu.edu

Kim Lyerly
Professor
Duke University
kim.lyerly@duke.edu

Paul Macklin
Associate Professor
Indiana University
macklinp@iu.edu

Umar Mahmood
Professor of Radiology
Massachusetts General Hospital
umahmood@mgh.harvard.edu

Kellie Malloy Foerter
Chief Clinical Development Officer
OncoSec Medical
kmalloy@oncosec.com

Steve Mao
Editor-in-Chief
Cancer Cell, Cell Press
stevemaodallas@gmail.com

Richard Marais
Director
Cancer Research UK Manchester Institute
richard.marais@cruk.manchester.ac.uk

Kim Margolin
Professor/Physician
Clty of Hope
kmargolin@coh.org

Jean-Christophe Marine
Professor
VIB KULeuven Center for Cancer Biology
jeanchristophe.marine@kuleuven.vib.be

Melanie Massenzio
Marketing Director
Novartis Pharmaceuticals
melanie.massenzio@novartis.com

Mark McLaughlin
Professor
West Virginia University
mark.mclaughlin@hsc.wvu.edu

Martin McMahon
Professor and Sr. Director
Huntsman Cancer Institute
martin.mcmahon@hci.utah.edu

Janice Mehnert
Phase I Clinical Program Director; Director of Melanoma Research
The Cancer Institute of New Jersey
mehnerja@cinj.rutgers.edu

Thorsten Mempel
Associate Professor
Massachusetts General Hospital
tmempel@mgh.harvard.edu

Glenn Merlino
Scientific Director for Basic Research
National Cancer Institute
gmerlino@helix.nih.gov

Jane Messina
Senior Member
H. Lee Moffitt Cancer Center jane.
messina@moffitt.org

Michael Meyers
Chief Medical Officer
Syndax Pharmaceuticals, Inc.
mmeyers@syndax.com

Martin Mihm, Jr.
Director of Melanoma
Brigham & Women's Hospital
martin.mihm@bwh.harvard.edu

Debbie Miller
Co-Founder
Tara Miller Melanoma Foundation
dmiller8375@gmail.com

George Miller
Co-Founder
Tara Miller Melanoma Foundation
gmiller@gmillerlawfirm.com

Sandra Misale
Research Associate
Memorial Sloan Kettering Cancer Center
misales@mskcc.org

Marsha Mitchum
Medical Officer
US Food & Drug Administration
Marsha.Mitchum@fda.hhs.gov

Nicholas Mitsiades
Associate Professor
Baylor College of Medicine
mitsiade@bcm.edu

Joao Monteiro
Chief Editor
Nature Medicine
joao.monteiro@us.nature.com

MRA Co-Founder and Board Chair Debra Black

Federico Monzon
Chief Medical Officer
Castle Biosciences, Inc.
fmonzon@castlebiosciences.com

James Moon
John Gideon Searle Associate Professor
University of Michigan
moonjj@umich.edu

Russell Moore
Field Medical Director
Pfizer Oncology
Russell.Moore@arraybiopharma.com

Eduardo Moros
Chief of Medical Physics
H. Lee Moffitt Cancer Center
eduardo.moros@moffitt.org

David Morse
Associate Member
H. Lee Moffitt Cancer Center david.
morse@moffitt.org

Rebecca Moss
R&D Clinical Program Lead, Melanoma
Bristol-Myers Squibb
rebecca.moss@bms.com

George Mueller
Managing Director
KKR
george.mueller@kkr.com

Aaron Newman
Assistant Professor, Department of Biomedical Data Science
Stanford University
amnewman@stanford.edu

Yevgeniya Nusinovich
Senior Editor
Science Translational Medicine
ynusinov@aaas.org

Steven O'Day
Executive Director
John Wayne Cancer Institute
odays@jwci.org

Marlana Orloff
Assistant Professor / MD
Thomas Jefferson University
marlana.orloff@jefferson.edu

Patrick Ott
Associate Professor
Dana-Farber Cancer Institute
patrick_ott@dfci.harvard.edu

Willem Overwijk
VP Oncology Research
Nektar Therapeutics
woverwijk@nektar.com

Fan Pan
Associate Professor
Johns Hopkins University
fpan1@jhmi.edu

Drew Pardoll
Professor of Oncology
Johns Hopkins University
dpardol1@jhmi.edu

Kristen Mueller, Senior Director, Science Program

Sapna Patel
Physician
UT MD Anderson Cancer Center
sppatel@mdanderson.org

Margie Patlak
Science writer
Margie Patlak, Inc.
margiepatlak@gmail.com

Elizabeth Patton
Programme Leader and Reader
MRC Human Genetics Unit, University of Edinburgh
e.patton@igmm.ed.ac.uk

Anna Pavlick
Professor of Medicine and Dermatology
NYU Langone Medical Center
anna.pavlick@nyumc.org

Guangyong Peng
Professor
Saint Louis University
gpeng@slu.edu

Weiyi Peng
Assistant Professor
University of Houston
wpeng2@central.uh.edu

George Peoples
Chief Medical Officer
Elios Therapeutics
georgepeoples2@hotmail.com

Rolando Perez-Lorenzo
Associate Research Scientist
Columbia University
rp2522@cumc.columbia.edu

Louise Perkins
President
BioPharmata Consulting
lmperkins@aol.com

Connie Pfeiffer
Head, US Oncology Advocacy & Prof Relations
Bristol-Myers Squibb
constance.pfeiffer@bms.com

Neil Pfister
Radiation Oncology Resident
Emory University
neil.pfister@emory.edu

Elena Piskounova
Assistant Professor
Weill Cornell Medicine
elp2025@med.cornell.edu

David Polsky
Professor of Dermatology
NYU Langone Medical Center
david.polsky@nyumc.org

Lara Porzak
President
Lara Porzak Photography
lporzak@gmail.com

Poulikos Poulokakos
Associate Professor
Icahn School of Medicine at Mount Sinai
poulikos.poulikakos@mssm.edu

Christine Pratilas
Associate Professor of Oncology
Johns Hopkins University
cpratil1@jhmi.edu

Richard Prejean
Senior Director, Team Lead
Pfizer
Richard.Prejean@arraybiopharma.com

Enrica Quattrocchi
Mayo Clinic
quattrocchi.enrica@mayo.edu

Shah Rahimian
VP of Clinical Development and Medical Lead
Idera Pharmaceuticals
srahimian@iderapharma.com

Ofer Reiter Agar
Fellow
Memorial Sloan Kettering Cancer Center
reiterao@mskcc.org

Jon Retzlaff
Chief Policy Officer, & VP, Science and Government Affairs
AACR
jon.retzlaff@aacr.org

Antoni Ribas
Professor of Medicine
UCLA
aribas@mednet.ucla.edu

David Rickles
Chief Science Officer
Radimmune Therapeutics
drickles@radimmune.com

Todd Ridky
Asst. Professor
University of Pennsylvania
ridky@pennmedicine.upenn.edu

Caitlin Riley
Patient Advocate
crileyri@gmail.com

Caroline Robert
Head of Dermatology
Gustave Roussy
caroline.robert@gustaveroussy.fr

Gavin Robertson
Professor
Penn State College of Medicine
gpr11@psu.edu

C. Daniela Robles-Espinoza
Assistant Professor
National Autonomous University of Mexico
drobles@liigh.unam.mx

Ze'ev Ronai
Professor
Sanford Burnham Prebys Medical Discovery Institute
ronai@sbpdiscovery.org

Richard Rosas
Product Manager. MBA
Novartis Pharmaceuticals
richard.rosas@novartis.com

Neal Rosen
Member
Memorial Sloan Kettering Cancer Center
rosenn@mskcc.org

Veronia Rotemberg
Assistant Attending
Memorial Sloan Kettering Cancer Center
rotembev@mskcc.org

Alicia Rowell
Vice Presdent
AIM at Melanoma
alicia@aimatmelanoma.org

Mark Rubinstein
Associate Professor
Medical University of South Carolina
markrubinstein@musc.edu

Kathy Russell
Principal
KR and Associates
klrussell411@gmail.com

Aditi Sahu
Research Scholar
Memorial Sloan Kettering Cancer Center
sahua@mskcc.org

April Salama
Associate Professor
Duke University
april.salama@duke.edu

Anthony Salvatore
Melanoma Medical Scientist
Bristol-Myers Squibb
anthony.salvatore@bms.com

Yardena Samuels
Associate Professor
Weizmann Institute
yardena.samuels@weizmann.ac.il

Bianca Santomasso
Assistant Attending
Memorial Sloan Kettering Cancer Center
santomab@mskcc.org

Ronit Satchi-Fainaro
Head, Cancer Research and Nanomedicine Laboratory
Tel Aviv University
ronitsf@post.tau.ac.il

Charles Saxe
Senior Scientific Director
American Cancer Society
charles.saxe@cancer.org

Barrett Scholl
VP, US Commercial Leader
Immunocore
barrett.scholl@immunocore.com

Ian Schuman
Partner
Latham & Watkins LLP
ian.schuman@lw.com

Gary Schwartz
Professor of Medicine, Chief, Division of Hematology Oncology
Columbia University
schwartzg@columbia.edu

Aleksandar Sekulic
Associate Professor, Dermatology
Mayo Clinic
sekulic@mayo.edu

Emilee Senkevitch
Science Officer
CDMRP-Melanoma Research Program
emilee.r.senkevitch.ctr@mail.mil

A. Hunter Shain
Assistant Professor
UCSF
alan.shain@ucsf.edu

Padmanee Sharma
Assistant Professor
UT MD Anderson Cancer Center
padsharma@mdanderson.org

Elad Sharon
Senior Investigator
National Cancer Institute
sharone@mail.nih.gov

T.J. Sharpe
Patient Advocate
Starfish Harbor LLC
patient1@tjsharpe.com

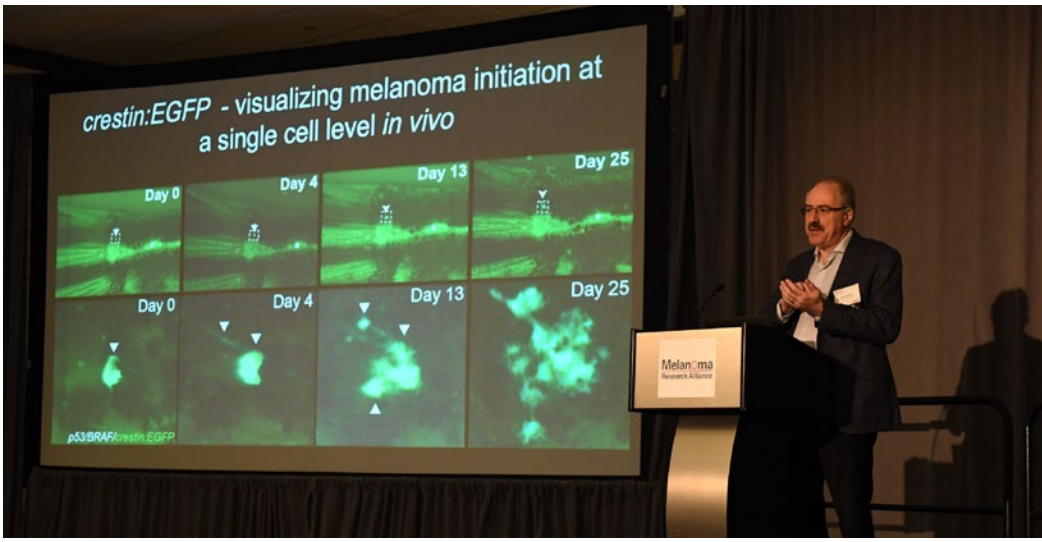
Elliott Sigal
Board of Directors
Melanoma Research Alliance

Fertram Sigurjonsson
President & CEO
Kerecis
gfs@kerecis.com

Jonathan Simons
President and CEO
Prostate Cancer Foundation

Anurag Singh
Assistant Professor
Boston University School of Medicine
asingh3@bu.edu

Craig Slingluff
Professor
University of Virginia
cls8h@virginia.edu



Leonard Zon of Boston Children's Hospital

Keiran Smalley
Professor and Director
H. Lee Moffitt Cancer Center & Research Institute
keiran.smalley@moffitt.org

Maria Soengas
Professor
Spanish National Cancer Research Centre
msoengas@cnio.es

Jonathan Sokoloff
Board of Directors
Melanoma Research Alliance

David Solit
Attending Physician
Memorial Sloan Kettering Cancer Center
solitd@mskcc.org

Vernon Sondak
Chair, Department of Cutaneous Oncology
H. Lee Moffitt Cancer Center & Research Institute
vernon.sondak@moffitt.org

Howard Soule
Executive Vice President and Chief Science Officer
Prostate Cancer Foundation
hsoule@pcf.org

Alan Spatz
Professor/Director of Pathology
McGill University Health Centre
alan.spatz@mcgill.ca

Neil Spiegler
Executive Director
Peggy Spiegler Melanoma Research Foundation
NSpiegler@aol.com

Stefani Spranger
Assistant Professor
MIT
spranger@mit.edu

Mark Stewart
Vice President, Science Policy
Friends of Cancer Research
mstewart@focr.org

Edward Stites
Assistant Professor
Salk Institute for Biological Studies
estites@salk.edu

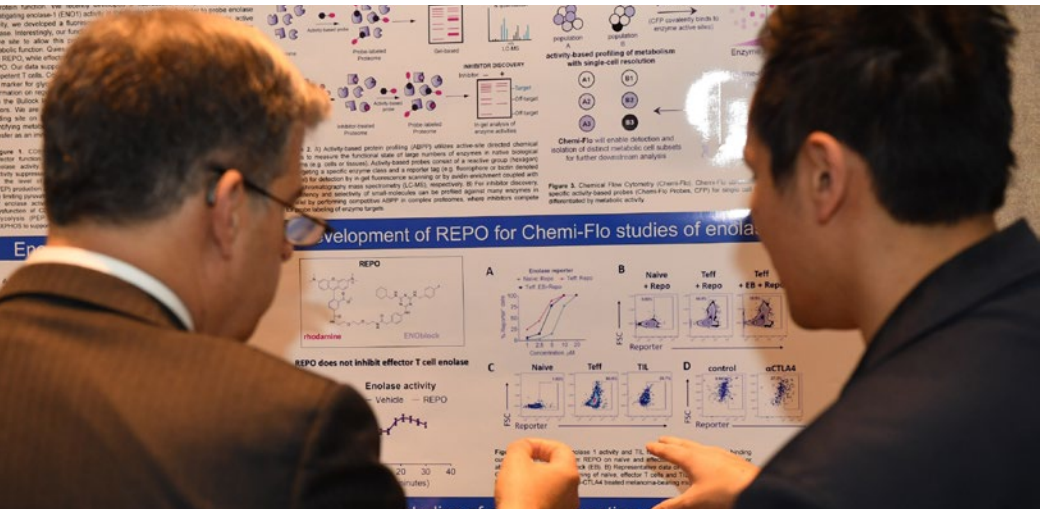
Erica Stone
VP of Oncology
GigaGen
estone@gigagen.com

Lorenz Studer
Physician
Memorial Sloan Kettering Cancer Center
studerl@mskcc.org

Ryan Sullivan
Assistant Professor
Massachusetts General Hospital
rsullivan7@mgh.harvard.edu

Lu Sun
Assistant Project Scientist
UCLA
lusun@mednet.ucla.edu

Qi Sun
Postdoctoral fellow
NYU Langone Medical Center
qi.sun@nyulangone.org



Susan Swetter
Professor of Dermatology; Director, Pigmented Lesion and Melanoma Program, Stanford Cancer Institute
Stanford University
sswetter@stanford.edu

Yuval Tabach
Senior Lecturer
Hebrew University
yuvaltab@ekmd.huji.ac.il

Mary Tagliaferri
Chief Medical Officer
Nektar Therapeutics
mtagliaferri@nektar.com

Elizabeth Tarka
Chief Medical Officer
Idera Pharmaceuticals
ltarka@iderapharma.com

Walter Tatarowicz
Senior Medical Science Liaison
Eisai, Inc.
Walter_Tatarowicz@eisai.com

Janis Taube
Director of Dermatopathology
Johns Hopkins University
jtaube1@jhmi.edu

Marc Theoret
Deputy Director (Acting), Office of Oncologic Diseases; Acting Associate Director, OCE
US Food & Drug Administration
marc.theoret@fda.hhs.gov

Magdalena Thurin
Program Director
National Cancer Institute
thurinm@mail.nih.gov

Roberto Tinoco
Assistant Professor
UC Irvine
rtinoco@uci.edu

Suzanne Topalian
Professor of Surgery and Oncology
Johns Hopkins University
stopali1@jhmi.edu

Olivia Tournay Flatto, PhD
President
Pershing Square Foundation
otflatto@persq.org

Remco van Doorn
Senior Researcher
Leiden University Medical Center
rvandoorn@lumc.nl

Morganna Vance
Medical Director
Novartis Pharmaceuticals
morganna.vance@novartis.com

Navin Varagarajan
Associate Professor
University of Houston
nvaradarajan@uh.edu

Francisca Vazquez
Associate Director
Broad Institute
vazquez@broadinstitute.org

Matthew Vesely
Instructor
Yale University
matthew.vesely@yale.edu

Jessie Villanueva
Associate Professor
The Wistar Institute
jvillanueva@wistar.org

Rachel Vogel
Assistant Professor
University of Minnesota
isak0023@umn.edu

Alfonso Waller
Associate Professor of Medicine
Rutgers New Jersey Medical School
ahw22@njms.rutgers.edu

Lixin Wan
Member
H. Lee Moffitt Cancer Center
lixin.wan@moffitt.org

Ashley Ward
Foundation Medicine

Jennifer Wargo
Associate Professor
UT MD Anderson Cancer Center
jwargo@mdanderson.org

Ian Watson
Assistant Professor
McGill University Health Centre
ian.watson2@mcgill.ca

Carmit Levy of Tel-Aviv University

Ashani Weeraratna
Chair and Professor
Johns Hopkins University
aweerar1@jhu.edu

Maria Wei
Professor
UCSF
maria.wei@ucsf.edu

Nadav Weinberg
Head of Nonprofit Partnerships
Tempus
nadav.weinberg@tempus.com

Grace Wenzel
Patient Advocate
egwenzel@gmail.com

Lyn Wenzel
Patient Advocate
wenzel.lyn@gmail.com

Richard White
Associate Member
Memorial Sloan Kettering Cancer Center
whiter@mskcc.org

Michael Wichman
Vice President
Anreder & Company
michael.wichman@anreder.com

Joshua Williams
Principal Scientist
Johnson & Johnson
jwill152@its.jnj.com

Brittany Wilson
COO
Helms Hope Foundation
brittany@helmshope.org

Jesse Wilson
Assistant Professor
Colorado State University
jesse.wilson@colostate.edu

John Wilson
Assistant Professor
Vanderbilt University
john.t.wilson@vanderbilt.edu

Melissa Wilson
Associate Professor of Medicine
Thomas Jefferson University
melissa.wilson@jefferson.edu

Megan Wind-Rotolo
Translational Medicine Team Lead - Immuno-Oncology
Bristol-Myers Squibb
megan.windrotolo@bms.com

Carl Winge
Dermatology Resident
Stanford University
mcgwinge@stanford.edu

Robert Wittig
Chief Operating Officer
RadImmune Therapeutics
rwittig@radimmune.com

Jedd Wolchok
Chief, Melanoma & Immunotherapeutics
Memorial Sloan-Kettering Cancer Center
wolchokj@mskcc.org

James Wooldridge
Chief Medical Officer
Checkmate Pharmaceuticals
jwooldridge@checkmatepharma.com

Xu Wu
Associate Professor
Massachusetts General Hospital
xwu@cbrc2.mgh.harvard.edu

Kai Wucherpfennig
Chair of Dept of Cancer Immunology & Virology
Dana-Farber Cancer Institute
kai_wucherpfennig@dfci.harvard.edu

Adam Yakovich
Senior Director, Medical Affairs
Replimune
adam.yakovich@replimune.com

Qin Yan
Associate Professor
Yale University
qin.yan@yale.edu

Iwei Yeh
Associate Professor
UCSF
iwei.yeh@ucsf.edu

Vashisht Yennu Nanda
Assistant Professor
UT MD Anderson Cancer Center
vynanda@mdanderson.org

Alexia-Ileana Zaromytidou
Chief Editor
Nature Cancer
a.zaromytidou@nature.com

Hassane Zarour
Professor
UPMC Hillman Cancer Center
zarourhm@upmc.edu

Li Zhou
Associate Scientist
Henry Ford Health System
lzhou1@hfhs.org

Jiyue Zhu
Professor
Washington State University
jiyue.zhu@wsu.edu

Robin Zimmerman
Scientific Research Advocate
Oregon Health & Science University
robin@wearesolsurvivors.org

Jonathan Zippin
Associate Professor
Weill Cornell Medicine
jhzippin@med.cornell.edu

Leonard Zon
Director, Stem Cell Program
Boston Children's Hospital
zon@enders.tch.harvard.edu

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Melanoma Research Alliance

Melanoma Research Alliance
730 15th Street, NW
Fourth Floor
Washington DC, 20005