

Reuniting the Melanoma Community

Features from the 2022 MRA Scientific Retreat

Melanoma
Research Alliance

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Letter from MRA's Scientific Staff



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One of the highlights for the Melanoma Research Alliance (MRA) each year is hosting the Annual Scientific Retreat. The 2022 Retreat was held March 9th through 11th, in Washington, D.C. One reason this is such a special event for MRA is that it brings together key stakeholders from across the melanoma research community, including academic researchers, representatives from industry, government and non-profits, and patients and their loved ones for three days of scientific presentations, conversations, and learning.

After a virtual convening in 2021, the 2022 Scientific Retreat marked a return to form where participants came together in person to hear about the latest discoveries in melanoma prevention, diagnosis, and treatment — many of which are being made by MRA-funded investigators. They also learned firsthand from individuals personally affected by melanoma and discussed ways in which the different sectors of the melanoma community can work together to ensure the momentum of the past decade of discoveries and treatment approvals continues.

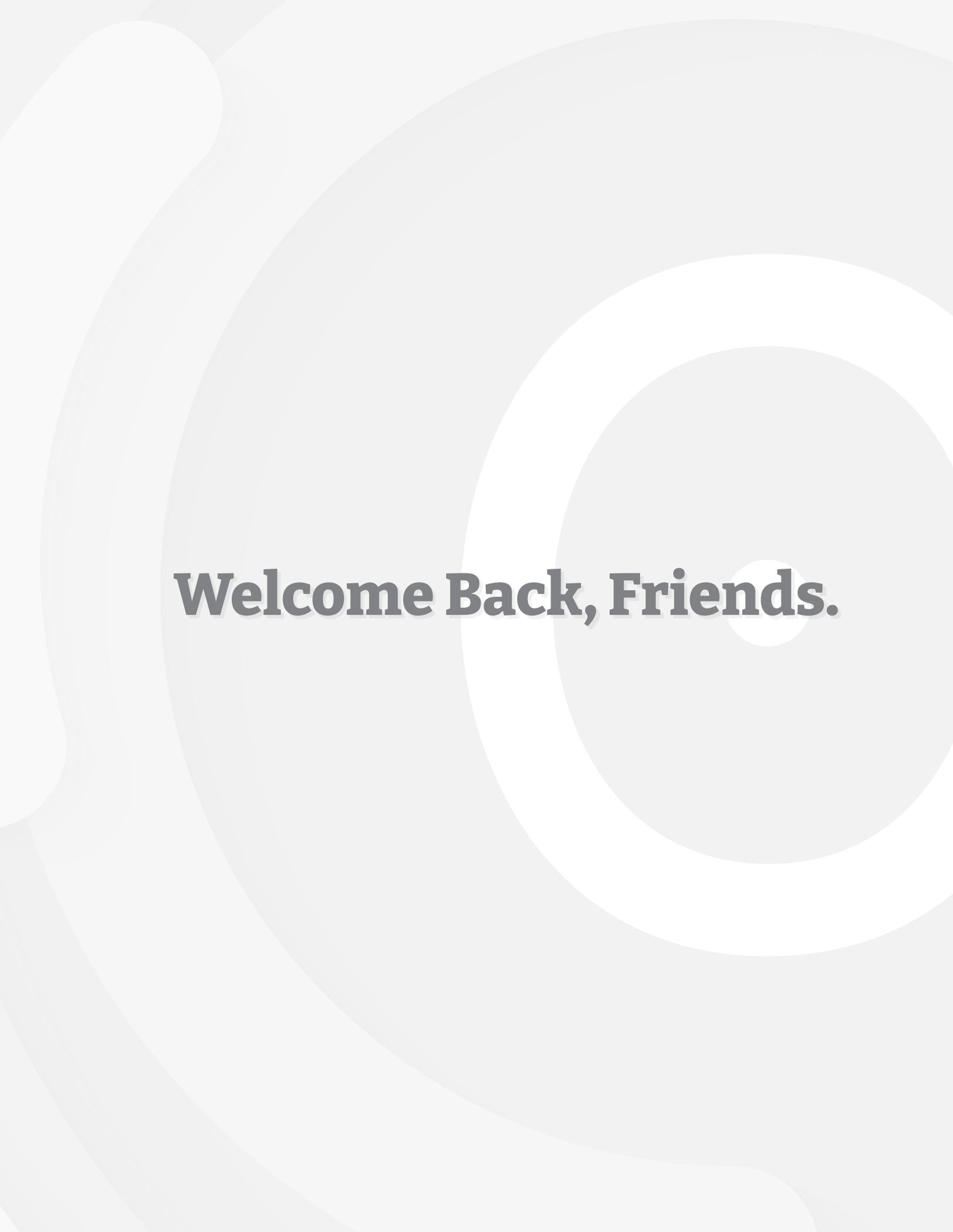
The scientific presentations touched on the incredible continuing momentum and recent progress in melanoma research and the many ways in which this has dramatically altered the treatment landscape. Topics discussed included novel treatment strategies, next-generation immunotherapies and strategies to address immune-related adverse events, as well as a variety of presentations by MRA Young Investigators. Together these presentations offered an exciting and in-depth picture of the current state of research and highlighted areas of unmet patient need.

Beyond the scientific sessions, the Retreat featured 20 distinct small group networking sessions focused on a variety of topics, including: melanoma prevention, diversity in the field, clinical trials, brain metastasis, vaccines, and rare melanoma subtypes. Twenty nine posters were presented across two sessions where Retreat participants could meet with the presenters for discussion. MRA's Young Investigators hosted a panel of leading academic journal editors to discuss navigating the publication process. A group of melanoma patient advocates also gathered to learn from one another and to hear updates on the latest science from leading melanoma researchers. Finally, researchers and clinicians gathered with representatives from industry and government to discuss how to best meet the needs of patients with treatment-resistant melanoma.

We at MRA are delighted and honored to host such important and productive conversations. We know they will spur the next wave of progress and lead to a day when suffering and death from melanoma will be a thing of the past.

Sincerely,

Marc Hurlbert Joan Levy
Tanisha A. Jackson Rachel Fischer



Welcome Back, Friends.



J.B. Ward – Patient Advocate

The Melanoma Research Community Reunites

Each year, MRA brings together hundreds of people from across the melanoma research community to exchange ideas, report on scientific progress, celebrate achievements, and mourn our collective losses.

This year, after going fully virtual for the 2021 program due to COVID-19, the 2022 Scientific Retreat also served as an in-person reunion and marked an official reset in face-to-face collaboration and networking.

To kick off the Scientific Retreat's many talks, panel discussions, and poster sessions, participants heard from J.B. Ward and Keith Tolley, both melanoma survivors who have benefited from recent advances in melanoma treatment options.

J.B. was diagnosed with vaginal mucosal melanoma just two months after celebrating the first birthday of her only child. She was told that she had a 5% chance of surviving five years. At the time, the number five became very important to her and she made a goal to get him to kindergarten. A few months later, she began what would become a year of intensive therapy for her melanoma. Ultimately, it worked. "I thought I'd be barely clinging to life — maybe in a wheelchair — but here I am. Full of life and looking forward to reaching the next phase with him and that's all thanks to all of you."

"I thought I'd be barely clinging to life ... but here I am ... and that's thanks to all of you."

J.B. Ward



Keith Tolley – Patient Advocate

“I just want to say thank you. Thank you for what you do and for being there for us... And please, please, never stop pursuing the cure.”

Keith Tolley

Keith opened his remarks by sharing a photo of his immediate family taken in December 2018. A week after the photo was taken, Keith underwent a liver biopsy that confirmed that he had Stage 4 melanoma. Keith underwent a series of treatments including clinical trials, multiple surgeries, combination immunotherapy, among others. “All of my treatments worked together synergistically...and by God’s grace, I stand here before you as a post-treatment melanoma survivor. I just want to say thank you. Thank you for what you do and for being there for us. And please, please, never stop pursuing the cure.”

With the impact of Keith and J.B.’s words still heavy in the room, participants welcomed Dr. Jason Luke to provide the Retreat’s opening keynote lecture. ●



The Tolley family



J.B. Ward and her son during her treatment and on his first day of kindergarten



Evan Lipson – Johns Hopkins University

The Changing Melanoma Landscape

Before 2011, the melanoma treatment arena was in a sustained drought during which patients were only offered a few treatments, and few with advanced stages of the cancer were still alive a year after starting treatment. In stark contrast, over the last decade, there has been a flood of new and highly effective treatments that have become available to patients, as well as a deluge of new promising therapies currently being tested in clinical trials. Taken together, this flood of activity has dramatically changed the melanoma landscape. Today, more than half of patients diagnosed with advanced melanoma and treated with these new therapies are alive five years after diagnosis. “Now we can really have durable disease control akin to a cure,” noted Hussein Tawbi of the University of Texas MD Anderson Cancer Center.

Thanks to clinical trials showing the effectiveness of treatments given to patients with early-stage melanoma, including treatments given before surgery, the chance of achieving a cure is even better, with fewer patients progressing to metastatic disease, added MRA-funded investigator Dr. Jason Luke of the University of Pittsburgh. “It’s a shifting landscape where we are giving treatment at earlier stages of disease,” he said. Combination treatments are also furthering better responses and are now standard of care, and studies are showing how to sequence treatments effectively when optimal results are not initially achieved.

Further shaping the melanoma landscape are two, first-in-class therapies, that recently received FDA approval for the treatment of melanoma. One is the first

Today, *more than half* of melanoma patients treated with new therapies are alive five years after diagnosis.



Jason Luke – University of Pittsburgh Medical Center

“Melanoma was the cancer that made cancer bad [a decade ago], and now it’s the cancer with perhaps the most therapeutic options than any other cancer out there.”

Jason Luke

drug approved specifically for melanoma of the eye (uveal melanoma), which traditionally resists many treatments. The other is a combination of the approved checkpoint immunotherapy, nivolumab, with another drug targeting a different immune checkpoint, called LAG-3 that boosts immune response to tumors. LAG-3 is a completely distinct immune checkpoint than those blocked by existing immunotherapies that target CTLA4 or PD1/PD-L1. And as researchers continue to uncover why about half of all melanoma patients don’t respond to current treatments, they are devising and testing many innovative therapies in thousands of clinical trials for melanoma and other cancer patients. “There are more agents on the horizon that may continue to expand our treatment options,” Luke stressed.

Choosing the Right Treatment Strategy

With more options come more choices, and recent clinical trial results continue to guide and inform clinical decision-making. Combination therapy with checkpoint immunotherapy or targeted therapies have proven more effective than single-agent treatments, but triplet therapies — that combine checkpoint immunotherapies with BRAF/MEK targeted therapies — have not generated as substantial a benefit as doctors hoped.

For patients with advanced BRAF mutant melanoma, the question of what treatment to give first — immunotherapy or combination BRAF-/MEK-targeted therapy — has been an open question. However, a new study called DREAM-SEQ showed that immunotherapies have outshined targeted therapies as first treatments because they generate more durable responses. Chair of MRA’s Medical Advisory Panel Dr. Michael Atkins, of Georgetown University, reported that

“DREAM-SEQ answered definitively that doctors should give immune therapy first rather than targeted therapy in patients with metastatic BRAF melanoma.”

He noted that a lot of patients given targeted therapies first went on to develop brain metastases, but that was rarely observed in patients who received and responded to immunotherapy first. “Most patients with Stage 4 disease probably have undetectable brain metastases at the time we’re starting to treat them, he posited, so the value of immunotherapy first is that it prevents relapse in the brain,” stressed Dr. Atkins.

Encouragingly, combination immunotherapy even works for patients with detectable brain metastases, Dr. Tawbi reported. “Three-year data from another clinical trial show 72% survival for a population of patients [with brain metastases] that a decade ago had less than a 20%, one-year survival so that’s a huge difference,” he said.

New Melanoma Drugs Earn FDA Approval

Opdualag Approved to Treat Advanced Melanoma

Only about half of patients with melanoma respond to even the latest treatments. So, Dr. Tawbi and others stressed the need for other new treatments and were impressed with those recently approved by the FDA. The new immunotherapy Opdualag — which combines novel immunotherapy relatlimab with PD-1 based nivolumab — significantly boosted progression-free survival compared to patients receiving nivolumab alone. Encouragingly, relatlimab did not substantially add to nivolumab’s serious adverse reaction rate. “The new combinations did not show



Michael Atkins – Chair, Medical Advisory Panel and Georgetown Lombardi Comprehensive Cancer Center



Marlana Orloff – Thomas Jefferson University

a lot more toxicity, but did show more benefits so we're really excited about those results," said Dr. Tawbi.

MRA-funded investigator Dr. Evan Lipson, of Johns Hopkins University, added that "This is a story that's just starting to be written," as there are almost a dozen compounds that target LAG-3 — which relatlimab targets — currently being tested.

KIMMTRAK Approved to Treat Metastatic Uveal Melanoma

MRA-funded investigator Dr. Marlana Orloff, of Thomas Jefferson University, reported on the newly approved drug called tebentafusp (KIMMTRAK), which targets a protein commonly found in uveal melanoma. These melanomas of the eye tend to be resistant to treatment. Initial testing in patients with uveal melanoma treated with multiple therapies before receiving tebentafusp had an impressive one-year survival of 70%. More advanced clinical testing found it nearly doubled one year overall survival compared to checkpoint immunotherapy, making it the new standard of care for patients with metastatic uveal melanoma, according to Dr. Orloff.

But she noted that not all patients with uveal melanoma have the molecular marker needed for the therapy to work. All patients treated with tebentafusp must have the HLA-A*02:01 variant gene, which is found in about 44% of White, 22% of Black, 19% of Asian/Pacific Islander, and 40% of American Indian/Alaskan people. Doctors will test for HLA-A*02:01 before prescribing tebentafusp.

"Tebentafusp has cracked the door open for us in the uveal melanoma world and there are a lot of drugs in clinical trials

now showing more promise than there have ever been," said Dr. Orloff.

She also highlighted the small group of patients in the study who were later treated with checkpoint immunotherapy after receiving tebentafusp. Tebentafusp appeared to resensitize these patients to the immunotherapy and they went on to double their initial response rate. This suggests that clinicians could improve patient response by how they combine and sequence tebentafusp with existing therapies. Another MRA-funded investigator Dr. Bill Harbour, from the University of Texas Southwestern, pointed out that relatlimab also holds promise for patients with uveal melanoma because its target (LAG3) is prominent in uveal melanomas.

Promising Experimental Therapies

Interleukin 2 has been used as a treatment for melanoma since the 1990s as it's known to stimulate an immune response to tumors. But it can cause so many serious side effects and has such a low response rate compared to current immune therapies that it rarely is used today. So, several people at the MRA Scientific Retreat reported their excitement about new experimental approaches to target interleukin 2 that are in clinical trials.

Also encouraging are clinical trial results of an experimental drug lenvatinib that targets a tumor growth factor pathway. When the drug in combination with pembrolizumab was tested in patients with advanced melanomas previously treated with other therapies, one-fifth of them responded to the innovative combination treatment, Dr. Tawbi noted.

“Now we can really have durable disease control akin to a cure.”

Hussein Tawbi



Hussein Tawbi – MD Anderson Cancer Center

“All of these trials may impact the standard of care over the next two to three years,” says Dr. Luke. “It’s really exciting to see how [better understanding of] the biology has fed forward into clinical trials that may change treatment options available for patients.”

Treating Patients at Earlier Stages of Melanoma

Treating patients with Stage 2 and 3 melanoma with systemic treatments after surgery, what is called adjuvant therapy, is becoming more common, several speakers noted. “Every time we find things that work in the metastatic setting, we want to see if they also will work earlier so we can cure patients before they become metastatic,” stressed Dr. Tawbi. He noted that patients with Stages 3B-D “have metastatic disease in disguise—the metastases are there but you just haven’t found them yet so you really have to do something about it.” It is now standard of care to treat patients with Stage 3 melanoma with the same drugs used to treat those with Stage 4 disease and studies reveal these drugs have similar effectiveness in both groups.

How intensively to treat these patients is still debatable, Dr. Tawbi noted, pointing out a study that found giving combination checkpoint immunotherapy to Stage 3 patients was not more effective than one immunotherapy drug alone. One-quarter of Stage 3 patients do not experience recurrence 10 years after diagnosis even without treatment, thus doctors also need to balance the possible benefits of systemic therapy with the risks of major side effects. So, both Drs. Atkins and Luke stressed the need for molecular markers indicating patients’ likelihood of experiencing side effects as well as markers that can indicate who is likely to benefit from adjuvant treatment — both important areas of future research.

Dr. Luke stressed that some patients with Stage 2B-C also have high-risk disease likely to recur and currently have worse survival than some patients with Stage 3 melanoma. In a clinical study he conducted, researchers showed the immunotherapy drug pembrolizumab improved recurrence-free survival at one-year following treatment in patients with Stage 2B/C melanoma, compared to no treatment, making it the standard of care for these patients, he claimed.

Researchers are also experimentally treating Stage 3 melanoma patients before surgery (called the ‘neoadjuvant’ setting) with encouraging results. Dr. Tawbi was excited to report that when clinicians gave such patients nivolumab with relatlimab before surgery, analysis of their tumor tissue following surgery revealed nearly two-thirds of them had a complete response with little to no major side effects. Studies are underway to determine if this neoadjuvant therapy offers more benefit than adjuvant therapy. However, Dr. Atkins stressed that neoadjuvant treatments have the added advantage of providing earlier signals to show whether treatments are working in patients’ tumors. Dr. Rodabe Amaria of the University of Texas MD Anderson Cancer Center also pointed out neoadjuvant therapy is a highly useful research tool. “I encourage any pharmaceutical company that has a new compound or combinations to invest in a neoadjuvant regimen because you can learn so much—response, safety, biomarkers—with a small investment in a few patients in a short period of time. The research potential with neoadjuvant treatment is unparalleled and should be considered moving forward,” she said.

Dr. Luke concluded his keynote talk by saying “Melanoma was the cancer that made cancer bad [a decade ago], and now it’s the cancer with perhaps the most therapeutic options than any other cancer out there.” ●



Rhoda Alani – Boston University School of Medicine

MRA Pioneers New Treatment Strategies

Over the last few decades, the melanoma research community has made tremendous progress detecting several genes that when altered cause melanoma, including those involved in melanoma’s growth and development. In addition, scientists have uncovered key enzymes that regulate the expression of critical tumor-associated genes — called epigenetic factors. Such “epigenetic” influences include enzymes called histone deacetylases (HDACs) and lysine demethylases (e.g. LSD1) both affecting the way in which proteins called histones interact with DNA leading to specific structural changes in the DNA ultimately regulating gene expression. Researchers have shown these epigenetic factors are involved in the drug resistance that melanoma patients acquire after being treated with targeted therapies, as well as with tumor progression and metastasis.

Consequently, a new area of investigation in cancer biology, and melanoma research in particular is to develop specific and sensitive therapeutic agents targeting these epigenetic factors. Some drugs have been developed that specifically inhibit HDAC and LSD1 but MRA-funded investigator Dr. Rhoda Alani, of Boston University, reported on the development of a novel “dual warhead” compound called corin that can block both. She anticipates this dual-action compound will aid in avoiding the development of rapid drug resistance seen with single-agent melanoma therapies, while also steering clear of the regulatory issues that can slow the development of combination therapies for cancer. She expects corin, the dual-action compound, to be more selective than current

Over the last few decades, researchers have made tremendous progress identifying gene alterations involved in melanoma initiation, growth, and development.



Both Drs. De Zio and Alani's research show the importance of therapeutically targeting proteins in a number of complex molecular pathways that play a unique role in cell growth, progression to metastasis, and the development of resistance.



Daniela De Zio – Danish Cancer Society Research Center (Denmark)

single-agent treatments for the same targets because of its ability to target enzymes existing in the same biological complex.

Dr. Alani's studies of corin in mice with melanoma found it significantly reduced tumor growth without causing serious side effects and that tumor growth inhibition was significantly improved over what was observed with either an HDAC inhibitor or an LSD1 inhibitor alone or in combination. Encouragingly, she also found that when she added corin to melanoma cells resistant to the effects of BRAF targeted therapies, the compound restored the cells' ability to respond to these drugs. Corin's effects on certain aspects of an immune response to cancer suggest it might also synergize with cancer immunotherapies, Alani said. While exciting preclinical data has been generated, more research is needed before moving this work into clinical trials.

MRA-funded investigator Dr. Daniela De Zio, of the Danish Cancer Society Research Center in Copenhagen, focused on a different molecular pathway involving a different enzyme, FAK1. FAK1 plays an important role in tumor growth and metastasis. Through her MRA Young Investigator Award, she discovered the role of FAK1 indirectly while studying the protein AMBRA1. Low levels of this protein expressed by the epidermis overlying a melanoma tumor is associated with a poorer prognosis. When she genetically knocked out the AMBRA1 gene in melanoma tumors grown in mice, not only did their tumors grow, they became metastatic, unlike the mice who still had the functioning AMBRA1 gene. Zeroing in further she found a loss of AMBRA1 enables melanoma cells

to take on the traits of invasive metastatic cells, including the ability to digest the matrix surrounding them and migrate.

Additional analyses in mice revealed that this transition to a more metastatic state depended on a lack of AMBRA1 triggering boosted FAK1 signaling. When she gave mice lacking AMBRA1 a FAK inhibitor "there was a dramatic reduction of tumor growth and invasion," Dr. De Zio said. "We propose FAK1 inhibition as a treatment strategy for melanoma patients whose tumors have low to no AMBRA1," she concluded. She is currently assessing the roles AMBRA1 and FAK1 in tumor samples from patients with early-stage melanoma and how these genes affect their responses to targeted and immune therapies.

Both Drs. De Zio and Alani's research show the importance of understanding and therapeutically targeting not just the flawed or altered genes identified in melanoma, but the proteins in a number of complex molecular pathways that play a unique role in cell growth, progression to metastasis, and the development of resistance.

MRA Young Investigator Dr. Ku-Lung (Ken) Hsu, of the University of Virginia, is working to uncover additional key proteins involved in melanoma — and the immune response to it — with the hope of discovering future therapeutic targets. A chemist by training, Dr. Hsu developed a new technique to determine the activity of proteins within single cells using fluorescent probes. Dr. Hsu noted that typical laboratory studies lump together



Ku-Lung (Ken) Hsu – University of Virginia



Simon Heidegger – Klinikum rechts der Isar, Technical University Munich (Germany)

hordes of cells and then analyze all the proteins they produce, but this bulk approach can miss important differences between cells. In addition, Dr. Hsu's novel probes are able to penetrate inside cells and can indicate when — and if — a specific protein is active. One of the probes designed to detect the activity of an individual protein can also report on a wider network of interacting proteins, which is key to understanding its mode of action. "If we can identify the proteins responsible for the mode of action of probe compounds, the hope is that we can start investigating these various proteins as therapeutic targets," Dr. Hsu said.

Dr. Hsu also expects his technique can help detect the most active tumor-fighting T cells which can then be harvested, multiplied, and reinserted back into patients with a type of melanoma treatment known as adoptive T cell therapy. At the 2022 MRA Scientific Retreat, Dr. Hsu reported he was able to use one of his probes to show how the activity of an enzyme involved in fueling T cells varies in different subtypes of T cells responding to tumors.

Another exciting new target for melanoma therapy is the important signaling that occurs between immune cells and tumor cells via 'tiny sacs' called vesicles released by tumor cells, Dr. Simon Heidegger of the Technical University of Munich reported. "It's a new paradigm in intercellular communication," he said. These extracellular vesicles (EVs) carry a vast array of molecules that can influence the behavior of the cells that receive them.

Although researchers traditionally suspected EVs enabled tumors to evade an immune response and fostered tumor progression, Dr. Heidegger discovered that tumor cells can produce immune-stimulating EVs when they are activated by key receptors inside cells that react to certain aberrant or foreign nucleic acids. This encounter prompts tumor cells to package the foreign tumor-specific nucleic acids into EVs that ultimately stimulates a T-cell anti-tumor response. In this way, these EVs actually enhance an immune response to tumors, Dr. Heidegger found from data generated in mice and human melanoma cells.

Further studies revealed that immune-stimulating tumor EVs synergized with checkpoint immunotherapies, rendering tumors previously resistant to checkpoint immunotherapies sensitive again. He also found that human melanoma cells generated EVs that primed T cells to attack melanoma. "Our data identified immunostimulated tumor cell-derived EVs as promising candidates for the development of personalized antitumor agents that could be combined with standard checkpoint immune therapies to overcome cancer therapy resistance," Dr. Heidegger said. ●



Maria Wei – University of California, San Francisco

Artificial Intelligence & Melanoma Detection: Closing the Gaps

The earlier a cancer is detected, the better the patient's prognosis. Melanoma typically develops first on an accessible part of the body—the skin—and appears on the outer layer of the skin before spreading horizontally as well as deeper into the skin. In short, the earliest signs of melanoma can be detected in the clinic. So early detection of melanoma is feasible and primary care physicians and dermatologists have “been trying to do the holy grail of catching and diagnosing melanoma early without the tradeoff of doing too many unnecessary biopsy procedures,” said Dr. Veronica Rotemberg, of Memorial Sloan Kettering Cancer Center, at the 2022 MRA Scientific Retreat.

But attaining that holy grail is challenging as detecting melanoma is currently based on subjective visual criteria and its accuracy varies greatly from practitioner to practitioner and clinic to clinic. “For lesions where it's very important to catch them early and accurately, the gold standard for that is perhaps not as golden as we would like,” said Dr. Maria Wei of the University of California San Francisco. “Melanoma screening as currently conducted is not very precise.” It can also be difficult to access, particularly for racial minorities, people who live in rural areas, the elderly and those on

Medicaid or lacking private insurance, she added. It can be challenging at times to get appointments with an expert dermatologist.

For all these reasons, researchers have developed artificial intelligence (AI) systems designed as tools to help doctors detect melanomas from photos of skin lesions. Initial testing of these systems was promising with several of them performing as well or even better than dermatologists evaluating the same photos. “Proof of principle doesn't mean proof of practice and whether we can bring these techniques into the clinic with confidence,” noted Dr. Wei.

She and Dr. Rotemberg pointed out several shortcomings of the currently available AI systems that suggest they aren't ready for prime time, including their inaccuracy for nonpigmented lesions, for patients with skin of color, and for skin disorders other than those on which they had been trained. The latter is especially challenging considering there are close to 3,000 different skin conditions, but many AI melanoma detection systems have only been trained on a small subset of them, Dr. Wei noted, and they “try very



Veronica Rotemberg – Memorial Sloan Kettering Cancer Center



Susan Swetter – Chair, Dermatology Council and Stanford University

hard to fit their diagnoses into diagnostic classes that they know,” she said.

Their accuracy also declines when they confront minor differences among images, such as changes in lighting, contrast, or even the positioning. The AI may accurately detect a melanoma under the ‘perfect conditions’ or when an image is in one position, but may miss the diagnosis when there is shadowing, hair, or if the image is turned upside down. This can lead not only to missing a melanoma when it occurs, but to unnecessary biopsies due to misdiagnosis. For example, nearly half the time AI confused scars with basal cell carcinoma, which may have necessitated a biopsy for confirmation.

The accuracy of AI systems can also vary from one clinic to another due to differences in how common melanoma is in each, or whether the clinic has a diverse patient population appropriately represented in the images used to train the AI system. Dr. Rotemberg noted. “I don’t want to say that this is scary or get people worried, but I just want us to think about the information we need when we’re trying to adjudicate whether AI should be used more widely,” she said.

She added that these AI systems may be substantially less accurate when confronted with rare melanomas, such as pediatric melanomas, which tend to look different than typical melanomas. And both she and Dr. Wei noted that the accuracy of AI systems may not be the same in minority populations underrepresented in the public data sets used to develop and train currently available AI systems. “It’s possible you won’t be able to take an off-the-shelf computer

model and use it on your entire population. You may have to supplement its training with the subpopulation(s) you’ll be using the model on,” Dr. Wei said.

AI systems lose their accuracy when images are blurred, unlike dermatologists, but they also seem to detect features that humans are not observing. “The fact that AI is evaluating lesions differently than doctors suggests that computer vision can augment provider diagnostics,” said Dr. Wei. She offers that rather than replacing dermatologists, AI melanoma detection systems will be used in conjunction with physician evaluations of suspicious lesions. “AI-based technologies can help us distill information to more useable degrees and to make more valid clinical decisions on that basis,” said Dr. Wei.

Drs. Wei and Rotemberg suggested several ways to improve AI melanoma detection systems, including expanded public image datasets that include a greater variety of ethnicities, races, and ages. Dr. Wei is partnering with the San Francisco General Hospital to create a dataset that’s much more diverse than those currently available. Dr. Rotemberg also suggested including more images in such datasets from rare melanoma subtypes and those taken from unusual anatomic sites.

“The horizon is really bright for improving AI tools for doctors to use, with a lot coming down the pipeline that can bring screening of melanoma into precision medicine and also address gaps in care with racial minorities and access issues,” said Dr. Wei. “It’s just not there yet.” ●



Researchers, clinicians, and government officials from FDA and NCI meet for the Industry Roundtable discussion.

INDUSTRY ROUNDTABLE

Tackling Treatment-Resistant Disease

The melanoma field has made incredible progress over the past decade in its ability to treat patients with advanced melanoma. This includes patients with tumors that cannot be entirely removed by surgery and patients whose tumors have spread to other parts of the body, referred to as metastatic melanoma. Since 2011, 15 new treatments have earned FDA approval, including targeted therapies directed at one of the most common genetically altered proteins in melanoma, BRAF, as well as various types of immunotherapies. However, while these pioneering advances have revolutionized the way in which melanoma is treated, not all patients yet benefit.

“Despite the progress made in the last 15 years to treat advanced melanoma, clinicians continue to struggle on a daily basis with patients who are not benefiting from all of the wonderful agents or combination of agents that have been brought forward,” said Ryan Sullivan, medical oncologist at Massachusetts General Hospital and MRA grantee. He was referring to the fact that a certain number of patients treated with targeted therapies and immunotherapies either do not respond to treatment at all, (refractory to treatment) or initially respond but then at a later point progress despite treatment (resistant to treatment). In either case, it is critical to identify new treatment options for this



“Despite the progress made in the last 15 years to treat advanced melanoma... clinicians struggle with patients who are not benefiting.”

**Ryan Sullivan –
Massachusetts General Hospital**



Mark Rutstein – Bristol Myers Squibb



Nageatte Ibrahim – Merck



Marc Hurlbert – Melanoma Research Alliance



Jonathan Simons – MRA Board of Directors and Marcus Foundation

patient population. To address this pressing topic, MRA as part of its 2022 Scientific Retreat convened a group of 40 representatives from industry, academia, and the FDA in a roundtable discussion on designing the most effective clinical trials to test novel drug combinations in patients not benefiting from approved therapies.

Designing the Best Clinical Trials to Address This Unmet Medical Need

“Patients now exposed to PD1 inhibitors that are no longer benefiting or are not benefitting right away is a very high unmet medical need and we have to make sure that we treat these patients with the right therapy once they become resistant,” offered Nageatte Ibrahim, Vice President of Oncology, Global Clinical Development at Merck and member of MRA’s Scientific Advisory Panel. There are factors to consider in setting up trials to test the effects of new drugs and/or combinations that may improve treatment effectiveness in this patient setting. Many clinical studies focused on patients with treatment resistant melanoma use a combination approach of testing a novel drug with continued administration of the same or a different checkpoint immunotherapy. The thought behind this approach is to determine whether the novel drug would improve the activity of the backbone therapy.

However, there are some concerns with this approach. If melanoma tumors do begin to respond to the combination, it’s not clear if this response is due to the novel therapy on its own or if it was the synergistic effect of both drugs combined. This begs the question as to whether continued treatment with the backbone immunotherapy is warranted.

Therefore, larger randomized clinical trials looking at the effectiveness of the novel agent alone versus the novel agent in the presence of a backbone checkpoint immunotherapy should be performed to sort out this important concern. Michael Atkins, Deputy Director of the Georgetown-Lombardi Comprehensive Cancer Center and Chair of MRA’s Medical Advisory Panel added: “As we learn more about the biology of immunotherapy-resistant tumors perhaps it would be better to combine a novel agent with something else other than a checkpoint immunotherapy.”

What Are the Considerations for “Special” Patient Populations?

While all patients with advanced melanoma can be treated with checkpoint immunotherapies, patients with tumors containing the BRAF mutation can also be treated with targeted therapies. However, until recently, doctors have had little prospective data to determine which treatment approach should be started first. Data from a recent Phase 3 randomized clinical trial showed that patients with a BRAF-mutation who were treated with an immunotherapy combo first (nivolumab + ipilimumab) followed by a BRAF/MEK targeted therapy experienced a greater 2-year overall survival (72%) compared with patients receiving the reverse sequence (52%). Based on these practice-changing results, more patients with BRAF-mutant melanoma will likely receive immunotherapy as first line therapy going forward. These results helped settle an important question facing clinicians.

However, with each question answered comes another to fill its place: If a patient with BRAF-mutant melanoma progresses, despite immunotherapy in the first line setting,



Suzanne Topalian – MRA Board of Directors, Chair, Scientific Advisory Panel, and Johns Hopkins University



Harriet Kluger – Yale School of Medicine



Caroline Robert – Gustave Roussy (France)

is a clinical trial or BRAF/MEK targeted therapy more appropriate? Several oncologists including Rodabe Amaria, medical oncologist at MD Anderson Cancer Center, said that “clinicians who have treated melanoma patients for many years will be able to distinguish BRAF patients who would benefit from being treated immediately with BRAF/MEK drugs from those who could potentially forego BRAF/MEK treatment — at least for a while — and proceed directly to a clinical study.”

“And what should we do with patients who progress and develop brain metastases? Are patients who have metastatic progression to the brain different? What are the criteria to include them in clinical trials?” asked Hussein Tawbi, medical oncologist at MD Anderson Cancer Center.

“There are different populations of patients with brain metastases and maybe we shouldn’t put all of them in the same category. Perhaps patients with asymptomatic brain mets can go into a clinical trial whereas patients with symptomatic mets might have to be placed immediately on additional or other treatments,” said Caroline Robert, Institut Gustave Roussy. Clearly following the characteristics of patients as they progress with brain mets and defining specific criteria to include them into clinical studies is important for the melanoma medical community to pursue.

Using Large Pooled Datasets to Further Define Clinical Trial Criteria

Designing the best criteria for randomized trials for patients with treatment resistant disease will require a more detailed understanding of the characteristics of patients who have

progressed after being treated with immunotherapy. “Large datasets can come from the analysis of pooled patient-level data from Phase 3 clinical trials. Companies follow Phase 3 study participants after they progress and receive long time survival information and data on subsequent therapies each participant received. Perhaps MRA is the right third party to pull this data together, which will be critical for informing better randomized clinical trial designs,” recommended David Berman, Head of Research and Development at Immunocore.

“This clearly was a lively discussion that resulted in a number of actionable items for us to follow-up on,” said Marc Hurlbert, Chief Executive Officer of the MRA. “We must continue to push forward to identify new therapeutic options for patients with treatment resistant melanoma.” ●



Russel Jenkins – Massachusetts General Hospital

The Final Frontier: Overcoming Treatment Resistance

About half of all patients given cancer immunotherapies do not respond to them, and although targeted therapies often dramatically shrink tumors in most patients, in about three-quarters of those responding patients the treatments stop being effective weeks to months after initially killing tumor cells. “That leaves a lot of room for improvement,” stressed Dr. Russel Jenkins of Massachusetts General Hospital. Fortunately, researchers have recently made progress in understanding what causes some types of resistance to immunotherapies or the acquired resistance seen in targeted therapies. This understanding is providing potential new treatment options to enhance response to current melanoma therapies.

Novel Triggers Leading to Resistance

Dr. Jason Luke, of the University of Pittsburgh, reported his lab and others have used different state-of-the-art genomic technologies to analyze tumors from patients unresponsive to current immunotherapies to identify ways in which the immune system can be turned on in these patients. His laboratory’s findings uncovered a number of important proteins that when targeted with drugs could enhance the effects of checkpoint immunotherapies — such as nivolumab and pembrolizumab — leading to better destruction of melanoma cells. His findings also revealed that the cell machinery that presents certain tumor specific proteins, called antigens, to train the immune system to destroy tumor cells can be defective in melanoma. “Treatments that augment antigen presentation could

About half of all patients given cancer immunotherapies don’t respond to them at all, or stop responding over time.



Antoni Ribas – University of California, Los Angeles

be high-priority strategies to take into the clinic,” Dr. Luke stressed.

One of those strategies was identified by a special technology called single cell transcriptomics done by MRA-funded investigator Dr. Jean Christophe Marine, of VIB in Belgium, and his colleagues. They found a master switch that enables melanoma cells to suppress antigen presentation. “This switch is a promising therapeutic target that could be blocked by existing drugs to make patients’ tumors more responsive to cancer immune therapies,” said Dr. Marine.

He also uncovered a different switch called PRRX1 that enables melanoma cells to migrate to other sites. PRRX1 is thought to play a role both in tissue repair and in cancer metastases and can be triggered in melanoma cells in response to targeted therapies. Dr. Marine and others found in mice and human melanoma cells. “These rare PRRX1-positive melanoma cells fuel metastasis in mice,” he said. Conceivably, a drug that blocks PRRX1 might enhance response to therapy and prevent melanoma metastasis.

Another therapeutic target to potentially boost response to commonly used checkpoint immunotherapies such as nivolumab or pembrolizumab is a protein called TBK1. Dr. Jenkins’ experiments using mouse and patient tumor-derived models found that when he blocked TBK1 on its own, he wasn’t able to reduce or stop tumor growth.



Leonard Zon – Harvard University

But when a TBK1 inhibitor was applied along with a checkpoint immunotherapy, the combination “dramatically sensitized tumor cells to die,” Dr. Jenkins said. “Our results demonstrate that targeting TBK1 is a novel and effective strategy to overcome resistance to immune checkpoint blockade.”

The Microbiome: Overcoming Bad Bacteria

Several researchers have also helped to uncover the major role that microbes (microscopic organisms like bacteria) in the gut have in influencing response to checkpoint immunotherapies. Investigators have recently zeroed in on a small group of intestinal bacterial culprits that consistently fuel cancer progression and lack of response to treatment in a number of studies. Dr. Laurence Zitvogel, of the Institut Gustave Roussy in France, reported that certain species of bacteria are found more commonly in the gut of patients with cancer compared to healthy individuals. These same species of bacteria become the dominant variety in the small intestine after many types of antibiotic treatments, crowding out “good” bacteria. She found the “bad” bacteria trigger stress molecular signaling that inflames the lining of the small intestine and boosts the number of T regulatory immune cells in the intestine. These cells then migrate to tumors where they suppress an immune response.

After uncovering the molecular pathway triggered by these “bad” bacteria, Dr. Zitvogel discovered that commonly used drugs called beta blockers could disrupt it. She found that



Roger Lo – University of California, Los Angeles

“There’s now an identified protein, ITCH, for developing agonists that can potentially synergize with targeted therapy in melanoma and prevent resistance.”

Roger Lo

when she gave the beta blocker drug propranolol to mice with tumors, it improved their response to immunotherapies. Others found that melanoma patients taking propranolol have improved survival. “Propranolol may be a good friend of melanoma patients,” Dr. Zitvogel stressed.

She also reported that when investigators gave melanoma patients unresponsive to immunotherapy fecal material containing the “good” bacteria of patients who responded to the immunotherapy, the non-responders overcame treatment resistance one-third of the time. In those cases, researchers found that the “good” bacteria from the responders had colonized in the gut of the previously unresponsive patients. The treatment also reduced the inflammation and signaling in the intestine thought to promote cancer progression. “This was good news for responders—the treatment completely reprogrammed their gut microbiome signaling,” said Dr. Zitvogel.

Combining Immunotherapy with Radiation to Overcome Resistance

Another potential way to overcome resistance to checkpoint immunotherapy faced by many patients is to combine immunotherapies with radiation therapy, Dr. Luke suggested. “Radiation can drive the enhancement of a T cell response,” he said. He also stressed that the treatment paradigm in radiation oncology is likely to change in the near term with the advent of the new technology called image-guided radiotherapy, which uses a molecular tracer to guide radiation towards multiple and often microscopic tumor sites. Such radiation therapy could be combined with immunotherapy and potentially could be quite effective.

More ITCH, Less Resistance?

Dr. Roger Lo and his colleagues at the University of California Los Angeles have been exploring what causes acquired resistance to targeted therapies. One way they approached this problem is based on their prior discovery that melanoma often times are more responsive to BRAF/MEK targeted therapy when the patients’ immune or T cells come into the tumor and join the fight. However, melanoma tries to get around the T cells by over-producing a protein called PD-L1. This suggests that a drug that can prevent this immune-escape strategy the tumor cells rely on might be a combination drug with BRAF/MEK-targeted therapy. Dr. Lo and his colleagues went to work to discover proteins that degrade PD-L1 in this situation, hoping to then uncover a compound which can activate this natural PD-L1-degrader. After extensive efforts on these fronts, they found that ITCH can degrade PD-L1 produced by the melanoma cells and that an ITCH activator or “agonist” could shut off the tumor immune suppression that occurs in mouse melanoma when they become or acquire resistance to BRAF/MEK targeted therapies. “There’s now an identified protein, ITCH, for developing agonists that can potentially synergize with targeted therapy in melanoma and prevent resistance,” Dr. Lo stressed.

“We have made significant progress to understand the root causes of resistance and identify new treatment strategies to make immunotherapies and targeted drugs more effective,” said MRA’s Chief Science Officer Marc Hurlbert. “But we still have a way to go to combat this critical problem and that is the reason why drug resistance remains as a top research priority for MRA.” ●

The MRA Melanoma Exchange Patient and Advocate Forum

MRA's **Melanoma Exchange Patient and Advocate Forum**, held in-person in Washington DC and virtually on March 9, 2022, brought together hundreds of melanoma patients, survivors, advocates, and their loved ones to provide lay-friendly, state-of-the-science education, promote collaboration, and provided networking opportunities across the melanoma community.

The forum brought 200 people together for the in-person and simulcast program. In addition, online videos from the event generated over 10,000 views in just one month — making this the most successful patient forum to date. Participants left 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 2022 **Melanoma Exchange Patient and Advocate Forum** are available at CureMelanoma.org/Forum



(L to R): Danielle Bello – Memorial Sloan Kettering Cancer Center, Hensin Tsao – Massachusetts General Hospital, and Rodabe Amaria – MD Anderson Cancer Center

Making Your Melanoma Journey Easier

Whether new to melanoma or well into your journey — as a patient, survivor, or caregiver — practical tips, strategies, and advice were shared at the 2022 MRA Melanoma Exchange Patient and Advocate Forum. Speakers at the Forum discussed what types of providers to seek, how to find information about your disease, how to advocate for yourself and your loved ones, and how patients and caregivers can find support.

Finding the Right Providers

If you notice a suspicious mole or other sign of melanoma: “Find the dermatologists and oncologists that specialize in melanoma, preferably ones connected to a large research center that can get you access to clinical trials and the best treatment available,” advised Christine Garrison. Christine’s daughter, Rebecca, died when she was 32-years old from melanoma that was initially misdiagnosed as benign by a dermatologist she saw for a fast-growing mole on her back.

“You need to remember that providers are humans [they can make mistakes], so it’s okay to question them and get second opinions,” stressed J.B. Ward, a survivor of a vaginal mucosal melanoma, whose first oncologist told her that there were no treatments for her type of melanoma and that she only had a 5% chance of surviving five years when she was diagnosed

Practical tips, strategies, and advice were shared with both new and veteran patients and advocates.

in 2016. However, she sought a second opinion at MD Anderson Cancer Center where she had a totally different experience. There, her provider was experienced with her rare type of melanoma and knowledgeable of the innovative immune therapies that were just becoming available. “I walked in and told her I had already gotten the bad news about my melanoma, but after she started to talk, I thought maybe it’s not as bad as I’d been told,” Ward said. She was successfully treated with immunotherapy and has now been disease free for five years.



Boris Bastian – Chair, Grant Review Committee and University of California, San Francisco



Marisol Soengas – Spanish National Cancer Research Centre (Spain)

“Trust your gut when it comes to your treatment and if something feels off, question it,” stressed Amy Jardon, a seven-year survivor of acral melanoma. Jardon, who blindly trusted her small-town oncologist, realized that her doctor had little to no experience treating her rare melanoma subtype that formed between her toes. “I always left her office wanting something more. I felt like I wasn’t getting good answers—no one explained that my melanoma was different. I finally decided it was not okay to walk out of the oncologist’s office with a queasy stomach and feeling like I’m not getting what I need to know,” Jardon said. Once she realized the screening advice the oncologist gave her was inconsistent and didn’t seem to be evidence based, she asked for a referral for a melanoma specialist in her state.

“This is where I should have been seen from the get-go,” she said. “At the melanoma medical oncology department, I felt like I came home. These people knew what acral melanoma was and could explain it to me. Feeling heard is so important. Trust your gut.” Jardon said.

Beyond just seeking out a melanoma specialist, Dr. Hensin Tsao — a dermatologist and researcher at Massachusetts General Hospital — emphasized the importance of seeking out a multidisciplinary team of providers that include dermatologists that specialize in melanoma, surgeons that specialize in cancer, and medical oncologists that have expertise with the type of melanoma you have. “You should

go to a center with a multidisciplinary melanoma clinic because they will have a multidimensional approach and be in tune with the latest developments,” he said.

Dr. Danielle Bello — a surgical oncologist and researcher at Memorial Sloan Kettering Cancer Center — agreed, noting that patients at these clinics will find out early in their care about clinical studies that might greatly impact their treatment options and outcomes. She gave the example of clinical trials currently exploring the use of checkpoint immunotherapies prior to surgery to remove their tumors. These innovative treatment strategies are showing promise in reducing the risk of recurrence for some types of early melanoma, and for improving outcomes for patients with advanced disease, as well as revealing what treatments might work for them in the future. “People have to know about clinical trials from the time they go to the dermatologist or surgeon’s office and not just when they go to their medical oncologist,” said Dr. Bello. “If a patient comes to a physician and isn’t informed about trials that are going on, it’s a missed opportunity.”

Dr. Rodabe Amaria — a medical oncologist and researcher at MD Anderson Cancer Center — added that people who live in rural areas, far away from major medical centers, aren’t entirely left out of potentially lifesaving clinical trials. “Cancer research occurs outside of these big centers so try to find clinics that participate in the National Cancer

“It felt like I was in a sea of people with cutaneous melanoma and nobody really understood my subtype, so finding those people who did was great.”

Amy Jardon

Institute’s Cooperative Groups, which engage in good research,” she said. To find out about clinical trials, one participant at the Forum suggested MRA’s Clinical Trial Navigator — available at CureMelanoma.org/ClinicalTrials — which provides patient-friendly information about available clinical trials, unlike clinicaltrials.gov, which is more oriented towards medical providers.

Finding the Right Information About Melanoma

Information can be empowering for some patients as long as it is the right kind of information, both Jardon and Ward stressed. When she searched the internet for information about melanoma, Jardon prioritized information provided by government organizations, such as the National Cancer Institute, trusted non-profit organizations like the Melanoma Research Alliance, and disregarded information that wasn’t current. Access other tips on getting up to speed after your diagnosis at CureMelanoma.org/JustDiagnosed.

“It gives the patient strength if they can make treatment decisions helped by people who have the knowledge they need,” a Forum participant offered. For those willing to dig deeper into more scientific findings, Ward suggested researching the latest on PubMed or other reputable online medical journals.

Finding a Supportive Community

Patients also need to find a supportive community, Ward, Garrison, and Jardon stressed. Ward and Jardon found it helpful to join or start Facebook groups that share information and provide support for people with their specific type of melanoma, as well as being a part of the MRA’s Melanoma Exchange online community — available at CureMelanoma.org/Community — where they

can connect with other people who also have these rare melanoma subtypes. “It felt like I was in a sea of people with cutaneous melanoma and nobody really understood my subtype, so finding those people who did was great,” said Jardon.

Ward added “Before I found the Facebook group for mucosal melanoma patients, it was very isolating. It’s been hugely helpful just connecting to people who are going through something similar and being able to mentor people just starting their melanoma journey.”

Supporting the Caregiver

Garrison noted that caregivers of loved ones with melanoma also need support. “Be sure you’re not alone as a caregiver and find someone who is willing to support you,” she stressed. She also suggested that caregivers take time each day to do something they enjoy and that centers their own wellbeing. “Some people need to take a walk out in nature while others need to hit their yoga mat or have a circle of friends they can see,” she added.

Jardon suggested contacting a local pharmacy or other resource that might have information about volunteers willing to relieve caregivers of their responsibilities for an hour or two. “Just because you are the caregiver doesn’t mean you have to do it 24/7. You need to take time for yourself as well as keep yourself healthy,” she said.

Another Forum participant stressed hiring people who can help with caregiving tasks, if possible, to allow you to spend more quality time with your loved one. “You can hire a caregiver but you can’t hire a wife, a daughter, a mother. Your loved one doesn’t need you to be cleaning toilets but rather sitting there reminiscing with them because you are the only person in the world that can do that for them,” she said. She added that many senior centers and the American Cancer Society have resources available for those that cannot afford to hire help.

Garrison pointed out that there are also support groups that provide emotional support for caregivers. She added that a year after her daughter died, she felt like she still needed support and that it helped to join the Melanoma Action Coalition. This coalition not only gave her practical support for the foundation she started in her daughter’s memory, but connected her to others who had lost loved ones to melanoma. “We don’t just support each other in organizational ways, but are very much a personal support community,” she said. ●



David Polsky – NYU Grossman School of Medicine

How Biomarkers Are Used in Melanoma

The term “biomarker” is a frequent buzz word in cancer care circles, but many patients do not understand what a biomarker is and how they are used in the clinic. At the MRA 2022 Patient Forum, Dr. David Polsky of New York University took away much of the mystery surrounding biomarkers by deftly explaining what they are and how they enter the market, as well as by showing how physicians use biomarkers to guide therapy and predict outcomes in their patients.

He reported that a biomarker is a measurable trait that can indicate a biological or disease-causing process, environmental exposure, or likely response to a treatment. For example, the BRAF mutation, found in about half of melanomas, indicates that the tumors have a genetic defect (mutation) that makes them likely to respond to the therapies that target it. “This biomarker is so good that we don’t even offer [BRAF-targeted treatments] to patients unless they have the [BRAF] mutation,” he said.

Dr. Polsky also noted, however, that biomarkers can sometimes accurately reveal an important biological trait but still not be clinically useful. For example, the protein on tumor cells, PDL1, can serve as a biomarker for PD1 directed checkpoint immunotherapies (ie Nivolumab and Pembrolizumab). Patients with high amounts of it are more likely to respond well to PD1 immunotherapy and have better survival than those that lack it. However — a subset of patients with negligible levels of PDL1 may still respond well to immunotherapy

A biomarker is a measurable trait that can indicate a biological or disease-causing process, environmental exposure, or likely response to a treatment.

Amie Bunker – Melanoma Research Program, CDMRP



— so the biomarker is not clinically useful for melanoma. “There’s a high bar that has to be overcome to incorporate a biomarker into clinical practice,” Dr. Polsky stressed. For a predictive biomarker, one that intends to ‘predict’ if a patient will respond to a given therapy, researchers must show that the biomarker substantially impacts the outcome of patients or that it influences treatment or other management choices. “Many biomarkers cannot achieve this,” he added.

Safety also has to be considered before rolling biomarkers into the clinic. If a prognostic biomarker, one that estimates the likelihood of recurrence, inaccurately predicts a patient’s cancer is likely to recur, it can cause harm by causing undue anxiety and unnecessary treatment. And if it inaccurately predicts a low risk of recurrence, it can cause harm by indicating treatment isn’t necessary when it might actually be beneficial.

The Food and Drug Administration (FDA) has to approve the safety and effectiveness of drugs before they can be used in the clinic. That approval is based on the results of well-done clinical trials in large numbers of patients. But most biomarkers are laboratory-developed tests that require a different level of testing and FDA approval before becoming commercially available. Their widespread use instead is based mainly on the strength of limited clinical testing done on them, whether doctors adopt them, and whether medical society guidelines support their use.

Dr. Polsky suggested that before doctors use a biomarker test on a particular patient, they consider whether the patient has similar traits to those on whom the biomarker was originally developed for. For example, a biomarker useful for melanomas originating in moles may not work for ones originating in the eye and vice versa, and a biomarker useful for advanced melanomas may not be valid for early-stage tumors.

Dr. Polsky reported that the commercially available DecisionDX-Melanoma for patients is a test that uses genetic analysis of tumor tissue to classify patients with Stages I and II cutaneous melanomas as to whether they are low or high risk for disease recurrence. It is intended to help physicians decide the appropriate follow up for these patients. But in one study the test did not improve the prognostic accuracy beyond the degree of tumor thickness and ulceration already used to classify early-stage patients and determine follow up. In another study the test did not prove useful for Stage I patients and needed further testing to make conclusions about the usefulness in Stage 2 patients. Consequently, the National Comprehensive Cancer



Nadia Jabri – Patient Advocate

Network (NCCN) guidelines oncologists tend to follow did not recommend routine testing with DecisionDX-Melanoma outside of a clinical trial.

In contrast, the blood-based test for levels of lactate dehydrogenase (LDH), a molecule melanoma cells secrete, is such a good predictor of prognosis, it is used to determine substaging for melanoma patients. LDH is also being tested to see if it can help suggest optimal treatment strategies for melanoma patients.

A biomarker Dr. Polsky is particularly excited about and currently testing in his lab is circulating tumor DNA (ctDNA), which is released into the blood mainly from dead or dying tumor cells or inflammatory cells. Physicians currently use the test in lung cancer patients to determine the mutations in their tumors so they can adjust their therapy appropriately. Because it is a blood test, it avoids the need for a lung biopsy in these patients, Dr. Polsky noted. Physicians also use levels of ctDNA in the blood to monitor disease in some patients “because it is a lot easier than going for a CAT scan and you can do it more often,” he said. A study Dr. Polsky and his colleagues recently conducted in patients with melanoma suggests that levels of ctDNA could also be an early indicator of treatment effectiveness and potentially used to guide therapy.

Researchers are currently testing a number of other promising predictive or prognostic biomarkers for melanoma, including molecular markers on tumors and those that measure cells or compounds circulating in the blood. During his introduction to the session, Dr. Burkhard Jansen — Chief Medical Affairs Officer at DermTech — stressed that “the use of biomarkers to guide clinical decision making has expanded dramatically and that this continues to be an exciting area of ongoing research.” ●

Melanoma Research Alliance



(L to R): Rachel Vogel – University of Minnesota, Maria Wei – University of California, San Francisco, Susan Swetter – Stanford University, and Tracy Callahan – Polka Dot Mama Melanoma Foundation

Sun Safety for the Melanoma Community

During a panel conversation focused on prevention at the MRA 2022 Patient Forum, Tracy Callahan, a five-time survivor of melanoma confessed that she became so afraid of getting another melanoma that she wanted to become a hermit. “I love the sun and traveling and suddenly I wanted to go nowhere and I was afraid to go to my kids’ baseball games,” she said. But eventually, “I realized that I had to start living life and that I could do it safely,” she said. Experts on the detection and prevention of melanoma on the panel agreed, pointing out several sun-safe strategies for patients diagnosed with melanoma and their families — including making sun exposure protection behaviors routine, conducting regular skin self-exams, and undergoing regular skin screenings with their dermatologist or oncologist.

Protect Yourself From the Sun

Dr. Rachel Vogel — an MRA-funded investigator at the University of Minnesota — stressed that sun exposure is the one risk factor for melanoma that people can control, unlike skin type or hair color. Yet her study found that one-third of melanoma survivors still experience a sunburn each year. Most of those sunburns are due to unintentional sun exposure, such as forgetting to use sunscreen or staying out longer in the sun than originally intended. When she gave melanoma survivors a wearable device that detects

There are several sun-safe strategies for melanoma patients and their families.



Joan Levy – Melanoma Research Alliance

and immediately reports the amount of sun exposure they were experiencing, she was able to reduce their total sun exposure per day by one-quarter throughout the summer. This proves that by increasing our awareness of our sun exposure, we can make a meaningful change to our behaviors — just like how a pedometer can help people take more steps.

Dr. Vogel stressed the importance of making sun protection behavior part of your everyday routine. “Maybe you put sunscreen on your face every morning or you keep an umbrella in your car so the next time you need it you have it with you,” she said.

MRA-funded investigator Dr. Maria Wei — of the University of California — stressed that physical barriers to the sun, such as broad-brimmed hats, long sleeves and long pants, and standing in the shade, tend to offer more protection than sunscreens alone. She noted you don’t have to necessarily wear UPF-rated clothing and that almost any clothing, except those with a loose weave, protects you from the sun. She also suggested using clear UV light filters for car side windows and the home. “You get a tremendous amount of sun through windows,” she said.

Stanford University’s Dr. Susan Swetter — a member of MRA’s Grant Review Committee, Dermatology Council, and Medical Advisory Panel — promoted the regular use of sunscreens, especially those from abroad that are more effective than those approved for use in the United States. “Sunscreen remains our best prevention along with protective sun behaviors and clothing, particularly in individuals with light skin who are at highest risk for melanoma,” Dr. Swetter said. She noted the FDA’s reluctance to approve new sunscreen ingredients due to safety concerns over the chemicals they contain, despite them being used over-the-counter worldwide for decades. There is also concern that sunscreens can damage coral reefs, but she stressed that this is a small and probably negligible reason for coral reef blight compared to rising ocean acidity, climate change, and ocean pollution. People from the US can order sunscreens from abroad or return from trips to other countries with them in their suitcases, Dr. Swetter noted and specifically suggested using sunscreens featuring the active ingredient tinosorb.

Dr. Wei noted now that studies show UVA rays from the sun can cause melanoma along with UVB, she expects the FDA to increase the amount of UVA protection that needs



Liz Patton – University of Edinburgh (Scotland)

to be in sunscreens. Currently, SPF measures how much UVB radiation is required to burn your protected skin versus the radiation exposure needed to burn unprotected skin. Unlike UVB radiation, UVA intensity is the same throughout the day, so exposure cannot be reduced by avoiding peak sun times. Dr. Wei also added that people often neglect to put the proper amount of sunscreen on their skin. Even in a study in which she taught people about proper usage of sunscreen, that lesson was usually forgotten 6 months later. She suggested sunscreens be dispensed by a pump that takes the guesswork out of measuring the right service size.

Unfortunately, practicing sun protective behavior won’t prevent people from developing melanoma in areas not exposed to the sun, such as the palms and soles and those found in the mucosal membranes, Dr. Swetter noted. But these melanoma subtypes are much rarer than those that arise due to sun exposure.

Regular Skin Cancer Self Exam

Another important strategy to prevent melanoma from being diagnosed at a more advanced stage is conducting regular self-exams of your skin and advocating for care when you detect something suspicious, panelists agreed.

“Get to know your skin and all your spots and bumps because any change in them might indicate cancer, because often the first sign of melanoma is a change in an existing mole. You don’t have to worry about anything you see



Tracy Callahan – Polka Dot Mama Melanoma Foundation



Menas Kizoulis – Johnson & Johnson

on your skin that stays the same, even if it looks quite alarming, which a lot of benign things do,” Dr. Wei stressed. She encourages her patients to take pictures of unusual spots on the skin and to have annual whole-body exams as part of their follow-up care. Dr. Swetter added that she encourages her patients to look for anything on the skin that stands out because it doesn’t resemble anything else, such as spots that are different in color or thickness.

The grown children, siblings, and parents of patients with melanoma might also want to consider getting screened regularly by a dermatologist, particularly if they are at high risk. But Dr. Wei noted that only about 5% of melanoma patients have an inherited genetic change that causes their melanoma and could be detected in their relatives with genetic tests. “The vast majority [of melanomas] are not genetic but more behavioral and related to where you live and the outdoor activities you do,” she said.

Dr. Swetter added that, “most of the time what melanoma patients’ relatives inherit is the same color skin, the same sensitivity to the sun, and they have shared environmental exposures, including all those trips to the beach.”

Dr. Swetter stressed that melanoma patients should educate their close relatives that they too could be at increased risk for melanoma and should consider screening for it. As for whether melanoma patients should have their young children screened by a dermatologist because

pediatric melanomas are so rare, Dr. Setter said it is not usually recommended that children be screened by anyone beyond a pediatrician. She added that a lot of pediatric melanomas are not sun-related, particularly in children with darker skin, and Dr. Wei added that moles typically develop slowly in children until they reach their teens or twenties.

In a nod to Ms. Callahan and others like her at the Patient Forum, Dr. Swetter said “We don’t want our melanoma patients to be hermits. We tell them to live a normal life and be outside and never refrain from enjoying life. You just have to be careful to use sun protection behaviors.” ●

“We don’t want our melanoma patients to be hermits ... You just have to be careful to use sun protection behaviors.”

Susan Swetter

Agendas

Wednesday, March 9

- 7:30am- 5:00pm Grant Review Committee Meeting (by invitation).....Milken Institute, 730 15th St NW, 2nd floor
- 11:45-5:30pm Melanoma Patients, Advocates & Foundations Forum.....J.W. Marriott, Salon II & III
- 4:00-8:00pm Retreat Registration open Foyer of Penn Avenue Terrace
- 6:00-7:30pm Opening Reception Penn Avenue Terrace**

Thursday, March 10

- 6:30am-6:00pm Registration..... Foyer of Salon III & IV
- 7:00-8:15am General BreakfastSalon II
- 7:00-8:15am Young Investigators Breakfast (by invitation) Salon I
- 8:30-8:45am Opening Remarks Day 1.....Salon III & IV**
Michael Kaplan, MRA President & CEO
Keith Tolley, Patient Advocate
J.B. Ward, Patient Advocate
Marc Hurlbert, MRA Chief Science Officer
- 8:45-9:15am Lecture**
Jason Luke, University of Pittsburgh – *Integrating clinical and genomic observations to advance combination therapies in melanoma*

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- 9:15-11:40am Session 1: Novel treatment strategies for melanoma**
Chair: C. Daniela Robles-Espinoza, National Autonomous University of Mexico
 - 9:15-9:40am Rhoda Alani, Boston University:**
The CoREST repressor complex as a mediator of phenotype switching and therapy resistance in melanoma
 - 9:40-10:05am Jiyue Zhu, Washington State University: Telomere homeostasis in melanoma**
 - 10:05-10:30am Break*
 - 10:30-10:55am Thomas Graeber, University of California, Los Angeles: Plasticity of extrachromosomal and intrachromosomal BRAF amplifications in overcoming targeted therapy dosage challenges**
 - 10:55-11:15am Daniela De Zio, Danish Cancer Society Research Center & University of Copenhagen:**
The tumor suppressor role of Ambra1 in melanoma
 - 11:15-11:40am Adam Hurlstone, University of Manchester: Fat uptake into and fat storage in melanoma cells promotes melanoma formation but are actionable targets**

11:40am-11:55am *Transition to lunch*

11:55am-1:20pm Networking Lunch and General Roundtables Salon I & II

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|---|--|
| 1. Acral + mucosal patient registry (salon H/J) | 11. Mentoring / mentorship |
| 2. Biomarkers | 12. Metastasis and tumor dormancy |
| 3. Brain metastasis and LMD | 13. Microbiome |
| 4. Clinical trials | 14. Neoadjuvant & adjuvant therapy |
| 5. Diversity | 15. Prevention |
| 6. Early detection & diagnosis | 16. Treatment – new targets & drug discovery |
| 7. Genomics | 17. Tumor microenvironment |
| 8. Intralesional therapies | 18. Vaccines |
| 9. irAE – understanding irAE | 19. Uveal melanoma |
| 10. Melanoma model systems | 20. Women in melanoma research and care |

1:20-1:25pm *Transition to general session room (Salon III & IV)*

1:30-3:00pm Session 2: Next generation immunotherapies and addressing irAEs Salon III & IV
Chair: Joan Levy, Melanoma Research Alliance

1:30-1:55pm **David Gerber, UT Southwestern: Trouble in paradise?** Immunotherapy selection, and toxicities

1:55-2:15pm **Ken Hsu, University of Virginia: Functional reporters of T cell metabolism for immunotherapy applications**

2:15-2:35pm **Simon Heidegger, Munich Technical University: Tumor-derived extracellular vesicles as personalized anti-tumor agents in melanoma**

2:35-3:00pm **Michal Lotem, Hadassah Medical Organization: Spliced immune receptors for immune regulation and melanoma immunotherapy**

3:00-3:30pm *Break*

3:30-4:30pm Session 3: Special Focus – Highlighting MRA Young Investigator Awardees
Chair: Kim Blenman, Yale University

3:30-3:40pm **Rachel Vogel, University of Minnesota: Effectiveness of a UVR-sensor wearable device intervention to improve sun behaviors and reduce sunburns in melanoma survivors**

3:40-3:50pm **Veronica Rotemberg, Memorial Sloan Kettering Cancer Center: Factors that influence automated melanoma detection**

3:50-4:00pm **Ed Stites, Salk Institute: Computational analyses of RAS/RAF pathway signaling**

4:00-4:10pm **Ashley Laughney, Joan & Sanford I. Weill Medical College of Cornell University: Single cell analyses reveal an unexpected link between epigenetic dysregulation and chromosomal instability in uveal melanoma progression**

4:10-4:20pm **Russell Jenkins, Massachusetts General Hospital: Targeting TBK1 to overcome resistance to cancer immunotherapy**

- 4:25-4:30pm** **Closing Remarks Day 1**
Rachel Fischer, MRA Senior Scientific Program and Registry Manager
- 4:45-6:15pm** **Poster Session I: Features Dermatology Fellow, Young Investigator,
Pilot Awardees, and Sponsors..... Salon I & II**
Light refreshments, all retreat attendees encouraged to attend

Dinner on Your Own: Explore DC, meet up with friends, or take it easy!

Friday, March 11

- 6:30-10:00am** *Registration open..... Foyer of Salon III & IV*
- 7:00-8:50am** *General BreakfastSalon II*
- 7:20-8:50am** **Poster Session II: Features Young Investigator Awardees Salon I & II**
- 7:30-8:50am** *Industry Roundtable Breakfast (by invitation) Willard Intercontinental, Willard Room*
- 9:00-9:05am** **Opening Remarks Day 2.....Salon III & IV**
Joan Levy, Senior Director, Special Scientific Projects
- 9:05-9:35am** **Lecture**
Laurence Zitvogel, Institut Gustave Roussy: *Impact of the intestinal microbiota on the clinical efficacy of immune checkpoint blockade*

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- 9:35-10:20am** **Session 4: Improving risk assessment & anti-tumor immunity in melanoma**
Chair: Shaheen Khan, University of Texas Southwestern
- 9:35-9:55am** **Maria Wei, University of California, San Francisco: *Applying artificial intelligence to melanoma screening and detection***
- 9:55-10:20am** **Leonard Zon, Harvard Medical School: *Craters on the melanoma surface serve as hubs for CD8+ T cells***
- 10:20-10:40am** *Break*

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- 10:40-11:30am** **Session 5: Understanding therapeutic resistance**
Chair: Roberto Tinoco, University of California Irvine
- 10:40-11:05am** **Roger Lo, University of California, Los Angeles: *Targeting adaptive immune resistance by degrading tumor cell-surface PD-L1 to promote anti-melanoma therapeutic efficacy***
- 11:05-11:30am** **Jean-Christophe Marine, VIB: *Charting dynamics & functional maps of the evolving melanoma ecosystem***

11:30am-12:30pm Panel Discussion: Treating melanoma in 2022: An evolving landscape

Moderator: Jonathan Simons (MRA Board Member)

Panelists:

- Rodabe Amaria, University of Texas MD Anderson Cancer Center
- Michael Atkins, Georgetown University
- Evan Lipson, Johns Hopkins University
- Marlana Orloff, Thomas Jefferson University

12:30pm-12:45pm Closing Remarks

Marc Hurlbert and Rachel Fischer

12:45-1:45 pm Lunch and DeparturesSalon II

- 11:30-11:45am **Registration & Check in***
- 11:45-1:00pm **Networking Roundtables with Lunch***
- 1:00-1:10pm **Welcome Remarks**
Michael Kaplan – President & CEO, Melanoma Research Alliance
- 1:10-1:45pm **Biomarkers: Lighting the Way**
From diagnosis to treatment selection, biomarker tests are increasingly being used to inform the care we receive. Learn what exists and how they're used.
David Polsky, MD, PhD - New York University Langone Health
- 1:45-2:45pm **One Step at a Time: A Melanoma Journey**
While no two melanoma journeys are exactly alike, similarities exist. Get tips and insight as this panel takes us through a hypothetical patient journey.
Danielle Bello, MD - Memorial Sloan Kettering Cancer Center
Hensin Tsao, MD, PhD - Massachusetts General Hospital
Rodabe Amaria, MD - The University of Texas MD Anderson Cancer Center
- 2:45-3:00pm **Break**
- 3:00-3:55pm **Step-by-Step: Living with Melanoma: A Panel Conversation**
Hear from this diverse panel of people who have been impacted by melanoma.
Amy Jardon - Melanoma Advocate
J.B. Ward - Melanoma Advocate
Christine Garrison - Vice President, Melanoma Action Coalition
Cody Barnett - Director of Communications & Patient Engagement, MRA
- 3:55 - 4:30pm **On the Horizon: Emerging Therapies to Watch**
The melanoma research landscape is advancing rapidly, with many clinical trials reporting positive results. Learn how these results are being translated into the clinic.
Hussein Tawbi, MD, PhD - The University of Texas MD Anderson Cancer Center
- 4:30 - 5:25 pm **Staying on the Path: Prevention for the Melanoma Community**
We all know the importance sun safety and prevention, but what does that really look like for people in the melanoma community? Get your questions ready for this interactive panel discussion.
Susan Swetter, MD - Stanford University
Rachel Vogel, PhD - University of Minnesota
Maria Wei, MD, PhD - University of California San Francisco
Tracy Callahan - President & CEO, Polka Dot Mama Melanoma Foundation
- 5:25 - 5:30pm **Closing & Wrap-up**

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