Melanoma Research Advances — 2019 in Review

Researchers expanded our understanding of treatment resistance, identified new treatment targets, and improved detection and prevention.

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During 2019, melanoma research continued its rapid pace of advancement, with FDA approval of a new adjuvant therapy treatment option, several first-in-human clinical trials, and significant progress towards earlier intervention. Researchers made remarkable progress in translational and basic research, focusing on expanding our understanding of treatment resistance, identifying new treatment targets, and improving melanoma detection and prevention.

For its part, the Melanoma Research Alliance (MRA) funded 46 new projects totaling $10 million, with an additional $1.5 million in funds matched or leveraged from outside sources in 2019.

MRA's 2019 research investments include:

- 34 new awards in our annual grants program,
- 9 awards made as part of our inaugural class of Dermatology Fellows, and
- 3 team science awards focused on melanoma metastasis, with two of the awards funded in partnership with the American Cancer Society.

New Adjuvant Therapy Treatment Option Approved by the FDA

Early in 2019, the US Food and Drug Administration (FDA) approved existing drug pembrolizumab (Keytruda) for use in the adjuvant setting for patients with lymph node involvement following complete lymph node dissection. Adjuvant therapy, delivered after complete surgical removal of melanoma, is intended to reduce the risk of melanoma returning. In clinical studies, adjuvant therapy reduced melanoma recurrence by 15-20% compared to the standard of care (careful monitoring). Without adjuvant therapy, an estimated 60% of Stage III melanoma patients will relapse within three years of surgical resection.

This new indication expands the number of approved adjuvant therapies to include: interferon

(Intron and Sylatron), ipilimumab (Yervoy), nivolumab (Opdivo), dabrafenib + trametinib (Tafinlar + Mekinist), and pembrolizumab (Keytruda) — giving patients and doctors more options.

Clinical Trials Launched to Develop New Treatments

In 2019, dozens of new clinical trials were launched to test the safety, dosage and effectiveness of new and refined melanoma treatments. Just a few examples include:

- Vedanta Biosciences launched a first-in-human trial in patients with metastatic cancer, including melanoma patients, to test experimental therapy VE800 in combination with the PD1 immune-checkpoint inhibitor nivolumab. VE800 is believed to modulate the microbiome to increase the immune systems' attack on tumors (NCT04208958).
- Evelo Biosciences launched a clinical trial to test its microbiome modulator EDP1503, in combination with the PD1 immune-checkpoint inhibitor pembrolizumab, among patients with advanced melanoma who did not respond to PD1 monotherapy. (NCT03595683)

In total, more than 500 melanoma-focused clinical trials are active in the United States, including over 300 that are actively recruiting patients. Learn more about clinical trials and how they may be right for you.

Testing Treatments Before Surgery — In the "Neoadjuvant" Setting

Over the last decade, significant progress has been made in better treating metastatic, Stage 4 melanoma. We've also seen many of the same drugs approved for stage 4 patients go on to earn approval in the adjuvant — or post-surgical — setting for patients with Stage 3 melanoma. Building on these successes, researchers have also wondered if giving the drugs before (rather than after) surgery — in the so-called neoadjuvant" setting — might be even more effective. There has been an explosion of clinical trials testing drugs and other treatments, including intralesional therapies, before surgery.

Neoadjuvant therapy for melanoma is not yet FDA approved and remains an area for research and clinical investigation. With the growing interest in the neoadjuvant field, MRA partnered with the FDA to convene a public workshop entitled Approaches to Neoadjuvant Treatment for Melanoma. The goals of the workshop were to help define which patients should be included in neoadjuvant clinical trials, how these trials are best designed, how to minimize the risk of adverse events for patients, and

how to select the optimal clinical trial endpoints. Videos, and archived presentations, from the workshop are freely available here.

Improving Detection, Diagnosis, and Prognosis

While approximately 90% of MRA research awards to date have focus on advancing melanoma

treatment options, MRA also invests in research needed to improve melanoma prevention, early detection, and to help inform disease prognosis. For example in 2019, MRA awarded five grants focused on tapping into the power of artificial intelligence and machine learning to advance research in detection, diagnosis, and prognosis.

In recognition of the important role that dermatologists can play in the prevention and early detection of melanoma, MRA also launched its Dermatology Fellows Program in 2019. The program aims to increase the number of early-career dermatologists that pursue a path in melanoma treatment and research. A call for proposals was launched in May, and the MRA Dermatology Council reviewed and selected nine inaugural awards out of a competitive pool of proposals. Funded projects range from piloting a telemedicine melanoma screening in a "minute-clinic" setting, employing AI and machine learning to aid in staging a newly diagnosed melanoma, to testing markers that can monitor for disease progression or recurrence.

Federal Advocacy Victory: Additional Funding for Melanoma Research

In late December, after months of advocacy on behalf of MRA and the Melanoma Research Foundation (MRF), Congress approved $20 million in funding for the Department of Defense (DoD)-funded Peer Reviewed Melanoma Research Program for FY 2020. This doubled the FY2019 appropriation and underscores Congress' understanding of the serious health risk posed by melanoma to Americans and American servicemembers. It also marks a significant achievement for the melanoma community and an important area of collaboration between two leading proponents of melanoma research.

Looking Ahead in 2020 — 'Triplets Therapies'

Several ongoing clinical trials are expected to report results in 2020. Melanoma researchers got an early highlight of some of these promising results in December, with the announcement from Genentech, a member of the Roche Group, of positive results in its Phase 3 trial testing "triplet therapy" in advanced melanoma. Genentech's triplet therapy combines the PD-L1 inhibitor atezolizumab (Tecentriq) to the combined BRAF/MEK targeted therapies cobimetinib (Cotellic) and vemurafenib (Zelboraf). We eagerly await the publication of the specific data result early this year. A similar ongoing triple-therapy Phase 3 trial from Novartis, combining the PD1 inhibitor spartalizumab to dabrafenib and trametinib, is also expected to report results this year, after publishing promising Phase 1 results in 2019.

MRA will continue to report on news related to new melanoma treatments, advances in early detection and diagnostic tests, as well as advances in prevention research throughout the year. Subscribe to our e-newsletter, follow us on Facebook and Twitter, or visit the MRA blog frequently.

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