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Melanoma Research Alliance

New Grants Totaling \$2.6 Million Fund Work to Reduce Immunotherapy Side Effects

American Cancer Society and Melanoma Research Alliance Fund Five Innovative Approaches

Atlanta, GA, May 10, 2018 – As the world marks Melanoma Awareness Month, the American Cancer Society (ACS) and the Melanoma Research Alliance (MRA) selected the first group of scientists to receive newly established research grants to investigate how to reduce rare, but serious, side effects resulting from cancer treatments with checkpoint inhibitors, a type of immunotherapy.

Last June, MRA and ACS formed a joint grant-making partnership with the goal of maximizing the overall outcomes for patients treated with checkpoint inhibitors and minimizing toxicity by finding ways to better predict, prevent, and/or minimize the side effects of this game changing treatment approach.

Checkpoint inhibitor drugs target certain proteins in cells called PD-1, PD-L1 and CTLA-4, which prevent T-cells from attacking cancer cells. The checkpoint inhibitor drugs allow the immune system to recognize and attack tumor cells.

Immunotherapy drugs have revolutionized melanoma treatment, and have also shown promise in treating several other cancer types including lung, head and neck, kidney, bladder, Merkel cell carcinoma, classical Hodgkin lymphoma, and MSI-H cancers. However, sometimes the treatments can also result in the immune system attacking healthy cells, which can cause a range of side effects from mild to sometimes life threatening.

Two researchers were granted the first ACS-MRA Multidisciplinary Team Awards:

Kai Wucherpfennig, M.D., Ph.D., Dana-Farber Cancer Institute, will conduct a clinical trial to discover whether it is better to treat patients' ipilimumab-induced colitis with steroids or the immunosuppressant infliximab. Ipilimumab is the first FDA-approved drug for metastatic melanoma patients. Some patients experience a variety of side effects, including inflammation in the colon (colitis), which if left untreated can be life-threatening. This study is designed to develop a better treatment for colitis that preserves the activity of the immune system against the cancer and to assess the cells and inflammatory molecules they produce which cause colitis that could be targeted in patients who do not respond to current therapies.

David Gerber, M.D., University of Texas Southwestern Medical Center, will conduct a large, multi-center clinical trial to determine if pre-existing, often clinically unknown autoimmunity, increases the risk of immune-related adverse events to immunotherapy. Dr. Gerber's goal is to build on data from a small pilot study in patients taking immune checkpoint inhibitors, which suggested that baseline levels of certain antibodies and proteins in the blood may be associated with risk of immune related adverse events. The goal is to improve treatment outcomes,

possibly increase under-used immunotherapy combination regimens, and possibly predict treatment efficacy.

Three researchers were granted the first ACS-MRA Pilot Awards:

Suephy Chen, M.D., Emory University, will focus on improving the understanding of cutaneous immunotherapy-related skin side effects in melanoma patients, which are often treated with steroids. In some cases, side effects can be so severe that patients choose to stop taking the therapy that might cure them of their deadly skin cancer, and do not take steroids. Dr. Chen's study includes clinical examination by a dermatologist, tissue samples of the rash, bloodwork, and surveys completed by patients, to characterize the skin side effects precisely. The goal is to be able to intervene early when a patient develops side effects and maybe even administer therapy that is tailored to the type of rash occurring.

Betina Yanez, Ph.D., Northwestern University. The goal of Dr. Yanez's research is to establish the feasibility of an evidence-based, web-delivered oncology program, "OncoLink" to improve the management of immune checkpoint inhibitor side effects. If found effective, OncoLink has the potential to improve the care of patients receiving immune checkpoint inhibitors and may improve clinical outcomes such as disease progression and survival.

Bianca Santomaso, M.D., Ph.D., Memorial Sloan Kettering Cancer Institute. Dr. Santomaso's research will focus on the relatively rare, but probably underestimated and poorly understood, neurologic immune-related adverse events or neurotoxicities, which can affect a patient's brain and nervous system. If a correlation between certain neurotoxicities and immune checkpoint inhibitors can be found, it could lead to the creation and refinement of clinical guidelines for identifying and treating these toxicities. Dr. Santomaso also plans to identify non-invasive candidate autoantibody biomarkers from patients who experience neurologic side effects after treatment with immune checkpoint inhibitors.

The grants are funded by MRA and ACS under a joint agreement. The multiyear grants go into effect July 1, 2018. MRA and ACS wish to acknowledge the generous support for their programs from individuals and Bristol-Myers Squibb, maker of the immunotherapy drugs ipilimumab and nivolumab.

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About the Melanoma Research Alliance:

Founded in 2007 under the auspices of the Milken Institute, with the generous support of Debra and Leon Black, the Melanoma Research Alliance exists to accelerate treatment options and find a cure for melanoma. As the largest nonprofit funder of melanoma research, it has dedicated more than \$100 million and leveraged an additional \$90 million towards its mission. Through its support, MRA has championed revolutions in immunotherapy, targeted therapies, novel combinations and diagnostics. Due to the ongoing support of its founders, 100 percent of donations to MRA go directly to its melanoma research program. MRA's ability to fund wide-ranging research in melanoma is amplified by unique collaborations and partnerships with individuals, private foundations, and corporations. Visit www.CureMelanoma.org for more information.

About the American Cancer Society:

The American Cancer Society is a global grassroots force of 1.5 million volunteers dedicated to saving lives, celebrating lives, and leading the fight for a world without cancer. From breakthrough research, to free lodging near treatment, a 24/7/365 live helpline, free rides to treatment, and convening powerful activists to create awareness and impact, the Society is attacking cancer from every angle. For more information go to www.cancer.org.