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SWOG Launches National Immunotherapy Clinical Trial for Rare Cancers

PORTLAND, OR – People with rare cancers now have the option of joining a national clinical trial testing leading-edge immunotherapies for a wide variety of tumor types. It's the first federally funded immunotherapy trial devoted to rare cancers. Despite their name, rare cancers make up more than 20 percent of cancers diagnosed worldwide.

The trial is called DART, which stands for Dual Anti-CTLA-4 & Anti-PD-1 blockade in Rare Tumors. It is managed by SWOG, the cancer clinical trials group that is part of the National Cancer Institute's (NCI) National Clinical Trials Network (NCTN). The trial is sponsored by the NCI and being conducted under the NCI collaborative agreements with Bristol-Myers Squibb for ipilimumab and nivolumab.

The trial draws on the design and takes advantage of the scale of another landmark trial offered through the NCTN – the NCI-Molecular Analysis for Therapy Choice, or NCI-MATCH, a precision medicine trial open at more than 1,000 clinical sites. Co-designed by the ECOG-ACRIN Cancer Research Group and the NCI, and led by ECOG-ACRIN, NCI-MATCH is the most sweeping precision medicine trial in the U.S. NCI-MATCH uses a customized tumor gene testing method to match patients with any solid tumor, along with lymphoma and myeloma, to multiple targeted treatments. Currently, there are 24 treatments offered, with plans to add about 10 more. Since NCI-MATCH was launched in August 2015, more than 2,500 patients have completed tumor gene testing out of the 6,000 patients intended to be screened. As of December 1, 2016, nearly 300 patients have entered treatment arms.

According to the definition used for the DART trial, rare cancers are those diseases with less than a 6 in 100,000 incidence per year. These include dozens of types, including cancers in nerves, glands, bones, and skin. But only certain patients will be eligible to enroll in DART. To join, patients must be registered to NCI-MATCH. If they don't have a treatment option under NCI-MATCH, or if they didn't respond to treatment on that trial, and their rare cancer is eligible, they can enroll.

DART patients will be treated with two immunotherapy drugs – ipilimumab plus nivolumab – a combination treatment that helps the immune system fight cancer. The U.S. Food and Drug Administration approved the combination to treat melanoma, and it

is currently being tested on a variety of lung cancers. Bristol-Myers Squibb sells the drugs under the brand names Opdivo (nivolumab) and Yervoy (ipilimumab).

Investigators leading the DART trial want to determine if this combination, given in six-week cycles, can significantly shrink tumors based on computerized tomography (CT) scans taken upon enrollment, then at regular intervals over the course of treatment. The DART team also wants to evaluate any side effects in patients, and estimate how long patients live and the length of time before their cancer progresses. In addition, a basic science team will use tumor tissue samples to study how immune cells and genes respond to the drug combination, and see if there are any biomarkers that predict treatment response among patients. Trial leaders plan to enroll 300 patients.

Dr. Razelle Kurzrock and Dr. Francis J. Giles are the DART senior study chairs, providing guidance on the trial design and protocol. Kurzrock is senior deputy center director at the University of California San Diego Moores Cancer Center and chair of the early therapeutics and rare cancers committee at SWOG, under whose auspices DART was developed. Giles is chief of the Division of Hematology/Oncology at Northwestern University Feinberg School of Medicine, deputy director of the Robert H. Lurie Comprehensive Cancer Center of Northwestern University, and SWOG principal investigator at Northwestern.

Dr. Sandip Patel is DART principal investigator.

“NCI-MATCH’s goal was to include rare cancer patients as part of the trial, and with DART, we hope to increase the impact by offering them this dual immunotherapy,” said Patel, assistant professor of medicine and assistant director of the Clinical Trials Office at UC San Diego Moores Cancer Center. “This trial is an extraordinary team effort between multiple cancer centers connected by SWOG.”

Dr. Young Kwang Chae, is principal investigator for the translational medicine component of DART and leads the study with Patel.

“DART could have strong science benefits by allowing us to explore the genomic landscape of rare tumors and their response to combination immunotherapy,” said Chae, assistant professor in the Division of Hematology/Oncology in the Feinberg School of Medicine at Northwestern and co-director of the division’s Developmental Therapeutics Program.

The DART team includes Dr. Donna Hansel, a pathologist and professor at UC San Diego; SWOG biostatisticians Megan Othus, Ph.D., and Melissa Plets, M.S., both of Fred Hutchinson Cancer Research Center; Dr. Christopher Ryan, SWOG executive officer for early therapeutics and rare cancers and professor at the Knight Cancer Institute at Oregon Health & Science University; SWOG protocol coordinator Cara Laubach; and Jeffrey Chuang, Ph.D., and Dr. Karolina Palucka from The Jackson Laboratory, a SWOG basic science partner. DART partners also include ECOG-ACRIN and the NCI’s Cancer

Therapy Evaluation Program. DART is funded by the NCI, with support from Bristol-Myers Squibb, which is providing the study drugs.

“We are hopeful that with the help of the rare disease community, and patients throughout the U.S., this pivotal trial will advance more treatments for people with rare cancers,” said Marcia Horn, SWOG’s patient advocate for early therapeutics and rare cancers and president and CEO of the International Cancer Advocacy Network.

SWOG *is part of the National Cancer Institute’s National Clinical Trials Network and the NCI Community Oncology Research Program, SWOG has nearly 12,000 members in 46 states and six foreign countries who design and conduct cancer clinical trials to improve the lives of people with cancer. Founded in 1956, SWOG’s 1,300 trials have led to the approval of 14 cancer drugs, changed more than 100 standards of cancer care, and saved more than 2 million years of human life. Learn more at swog.org.*