Friends of Cancer Research Announces New Project

HRD Harmonization Project to Create Consistency in HRD Use

Washington, DC – December 9, 2020 – Friends of Cancer Research (*Friends*) is proud to announce its latest research partnership, the HRD Harmonization Project. Homologous recombination deficiency, or HRD, is a complex biomarker that has much promise in identifying patients with certain cancers who are more likely to benefit from PARP inhibitors and additional DNA repair targeting drugs in the future.

Currently, there is no standardized way to define, measure, and report HRD. As such, *Friends* has assembled a consortium of project partners from key healthcare sectors to address concerns about the lack of consistency in determining HRD status, its prognostic value, and its use as a predictive biomarker. A similar gap in standardization was also the impetus behind the *Friends'* tumor mutational burden (TMB) Harmonization Project.

"Harmonization regarding measurement and use of HRD as a predictive biomarker will help ensure patients receive the best treatment for him or her," said Friends of Cancer Research President & CEO, Jeff Allen. "Without greater alignment to defining and measuring HRD, there will continue to be confusion around its use in the clinic and its role in drug development, potentially leading to less favorable results for patients."

HRD has been associated with improved patient response to treatments, including platinum-based chemotherapy and PARP inhibitors. Given the improved outcomes associated with patients whose tumors display characteristics of HRD, it is vital to understand what should be measured, how to achieve alignment on how HRD is measured, and its performance as a biomarker for treatment efficacy.

"Understanding what exactly HRD is, how to accurately assess and measure the degree of HRD in a tumor, and how this affects outcomes or response to treatment in patients continues to be confusing to clinicians, patients, and researchers," said Rebecca C. Arend, Associate Professor at the University of Alabama at Birmingham. "Therefore, a project that is as non-biased as possible in breaking down the silos between diagnostic companies and drug companies in order to better understand and define HRD is extremely important."

The HRD Harmonization Project will be broken down into three phases. The first phase is currently underway and consists of a landscape analysis on the current practices in the field regarding HRD.

"Foundation Medicine is committed to providing reliable insights to inform treatment decisions for cancer patients, which requires deep collaboration throughout the ecosystem and consistent, high-quality standards across cancer care," said Jeffrey Venstrom, Senior Vice President of Clinical Development at Foundation Medicine. "We are excited to partner with Friends of Cancer Research,

the FDA, and the cross-industry group on this important HRD effort, which will fundamentally help us ensure that the right patient is receiving the right therapy at the right time."

By the end of phase 1, the consortium aims to have agreement on the definition of HRD and the parameters that contribute to the determination of HRD status (HRD-positive/negative). Additionally, the consortium will create recommendations and best practices to benefit the entire cancer community.

"Friends of Cancer Research has an established track record in promoting understanding of diagnostics and assay harmonization and AstraZeneca is pleased to support their efforts," said Andy Williams, Precision Medicine Franchise Leader, Lynparza Diagnostics at AstraZeneca.

"As a leader of the HRD Harmonization Project, *Friends* can help the physician, laboratory, and patient communities understand the different methods and select high-quality options to measure HRD," said Tim French, Senior Global Medical Affairs Leader, Diagnostics at AstraZeneca.

Results from Phase 1 of the HRD Harmonization Project are slated to be released in the first quarter of 2021.

Project partners participating in Phase 1 of the project include: Abbvie, Ambry Genetics, AstraZeneca, Arizona State University, Bristol Myers Squibb, Caris Life Sciences, EMD Serono, Foundation Medicine, GlaxoSmithKline, Guardant Health, Janssen, Merck, Myriad, the National Cancer Institute, Novartis, Pfizer, Resolution Biosciences, Tempus, Thermo Fisher, University of Alabama at Birmingham, University of Heidelberg, and the U.S. Food and Drug Administration.

About Friends of Cancer Research

Friends of Cancer Research (*Friends*) is working to accelerate policy change, support groundbreaking science, and deliver new therapies to patients quickly and safely. We unite scientists, pharmaceutical companies, and policy makers with shared trust and guide them toward meaningful cooperation. This collaboration among partners from every healthcare sector ultimately drives advances in science, policy, and regulation that speed life-saving treatments to patients. For more information, please visit https://friendsofcancerresearch.org/.