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New Manuscript Shows Changes in ctDNA Reflect Clinical Benefit to Patients

Washington, DC - August 15, 2022 - A new manuscript by Friends of Cancer Research (*Friends*) published in JCO Precision Oncology, finds strong associations between reductions in circulating tumor DNA (ctDNA) levels from on-treatment liquid biopsies with improved overall survival and progression-free survival in non-small cell lung cancer (NSCLC). This manuscript highlights results that provide the initial basis of *Friends*' ongoing ctDNA for Monitoring Treatment Response (ctMoniTR) project.

"This study provides foundational evidence that ctDNA serves as an early indicator of treatment response," said Dr. Jeff Allen, President & CEO of Friends of Cancer Research. "The unique approach of the ctMoniTR project brings together data from multiple, independent studies to enable faster and more robust analyses than if any one organization were working alone."

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The ctMoniTR project will soon be expanded to include additional tumor types, stages, and drug classes to further validate the association between changes in ctDNA levels and clinical outcomes in additional clinical settings. Data from over 20 clinical trials are currently being collected for the *Friends* ctMoniTR Step 2 Project and analyses will begin later this year. With a specific focus on evaluating how early changes in ctDNA are associated with treatment outcomes, ctMoniTR will provide a harmonized approach to further characterize the role ctDNA can play in accelerating the development of new cancer treatments for patients.

To complement these meta-analyses, *Friends* is also working with stakeholders from industry, government, academia, and patient groups to develop an evidentiary roadmap that will support the use of ctDNA in regulatory decision-making. Findings from the draft roadmap were presented in a public virtual meeting on July 20. Our goal is to develop an aligned strategy so that as data continue to be collected in the coming years, it can be used to support the development of community standards and alignment to efficiently validate ctDNA as an early endpoint. For more information: https://friendsofcancerresearch.org/ctdna/

Friends of Cancer Research is proud to partner with the following organizations on this important topic:

Cancer Research And Biostatistics (CRAB), NMD Group LLC, University of Pennsylvania Perelman School of Medicine, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University School of Medicine, Bristol Myers Squibb, Washington University School of Medicine, Guardant Health Inc., AstraZeneca, GRAIL, Roche Sequencing Solutions, Merck Research Laboratories, Food and Drug Administration (FDA), Genentech Inc, Penn Medicine, Roche Diagnostics, Bayer, Biodesix, Boehringer Ingelheim, EMD Serono, Inc., Foundation Medicine Inc., Illumina Inc., Lilly Oncology Inc., Molecular Characterization Laboratory (MoCha) at Frederick National Laboratory, Natera Inc., Novartis AG, Pfizer Inc., Princess Margaret Cancer Centre, Regeneron Pharmaceuticals Inc., Resolution Bioscience Inc., and Takeda Pharmaceutical Company.

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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/.

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