MPAACT Consortium Unites Industry and Academia to Establish Measurable Residual Disease as a Surrogate Endpoint in Acute Myeloid Leukemia Drug Development

Validated Measurable Residual Disease Assays are Critical for the Rapid Development of Future Novel Therapeutics for Patients with Acute Myeloid Leukemia

SPRING HOUSE, Pa., May 5, 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today the Measurable residual disease Partnership and Alliance in Acute myeloid leukemia Clinical Treatment (MPAACT), an industry-led research alliance founded in 2018 between Janssen Research & Development, LLC, Genentech (a member of the Roche Group), Novartis, and Celgene Corporation, a wholly owned subsidiary of Bristol Myers Squibb, and recently expanded with additional members Amgen, AbbVie, and Kronos Bio, is advancing efforts to establish measurable residual disease (MRD) as a surrogate endpoint for overall survival in the treatment of acute myeloid leukemia (AML).

AML is a difficult to treat blood cancer with significant unmet medical need as one of the most common types of leukemias in adults and a five-year relative survival of less than 30 percent¹. Clinical trials for new therapies in AML are becoming increasingly lengthy to complete based on the traditional clinical endpoint of survival. MRD is a measure of the number of cancer cells that remain

after chemotherapy in patients and its presence is associated with survival.\textsuperscript{2,3} Undetectable MRD (uMRD), sometimes referred to as MRD-negativity, means that residual cancer cells were not detected using a specific and highly sensitive test. While it is frequently defined as less than one cancer cell in 10,000 leukocytes, the threshold may vary by cancer type. Formally establishing MRD/uMRD association with overall survival (OS) requires a unique collaborative effort where a surrogate clinical endpoint may aid in enabling faster development and patient access to novel therapies.

Together, MPAACT and the AML academic community will contribute data across multiple clinical trials with the goal of establishing MRD as a surrogate endpoint for OS in clinical trials of new therapies being studied for AML. The Mayo Clinic Statistics and Data Management Center, an independent statistical partner led by Qian Shi, Ph.D., Rochester, MN, will perform the meta-analysis to assess association of MRD with OS.

“I have been working with MPAACT since its inception and am gratified that many key academic investigators and industry collaborators in the AML field have been able to come together to pool data, resources, creativity, and intellectual strength to investigate the role of MRD as a surrogate endpoint for overall survival in AML,” said Gail Roboz\textsuperscript{*}, M.D., Professor of Medicine and member of the Sandra and Edward Meyer Cancer Center at Weill Cornell Medicine, and an oncologist at New York-Presbyterian/Weill Cornell Medical Center. “Measuring MRD as a surrogate endpoint may help forge a path to bring new AML therapies to patients quickly.”

MPAACT also aims to validate MRD testing methodologies including next generation sequencing and flow cytometric assays, and provide the basis for high quality and consistent testing of MRD in future AML clinical trials.

The consortium looks to continue to bring together its expertise with those in the field through joint advisory boards, congress presentations and other scientific engagements.

**About Acute Myeloid Leukemia**
Acute myeloid leukemia (AML) starts in the bone marrow (the soft inner part of certain bones, where new blood cells are made), but most often the disease quickly moves into the blood, as well. It can sometimes spread to other parts of the body including the lymph nodes, liver, spleen, central nervous system (brain and spinal cord), and testicles. Most often, AML develops from cells that would turn into white blood cells (other than lymphocytes), but sometimes AML develops in other types of blood-forming cells.\(^4\)

**About the Janssen Pharmaceutical Companies of Johnson & Johnson**
At Janssen, we’re creating a future where disease is a thing of the past. We’re the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.


*Dr. Roboz has served as a paid consultant to Janssen.

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*Cautions Concerning Forward-Looking Statements*

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