FDA Approves First Therapy for Patients With MRD-Positive ALL

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SEATTLE, WA, April 2, 2018 – Adaptive Biotechnologies, a leader in next-generation sequencing (NGS) of the adaptive immune system, applauds the U.S. Food and Drug Administration (FDA) for its recognition of minimal residual disease (MRD) as an actionable indicator that can guide treatment decisions for patients with acute lymphoblastic leukemia (ALL). This is evidenced by the FDA's decision last week to grant accelerated approval of a supplemental indication for Amgen's drug BLINCYTO ® (blinatumomab) for the treatment of B-cell precursor ALL in first or second complete remission with MRD ≥0.1% in adults and children. This new indication marks the first time the FDA has approved a therapy based on MRD status.

In 2016, Adaptive and Amgen entered into a collaboration to develop a validated MRD assay. The FDA's approval of BLINCYTO for MRD-positive ALL patients provides support for the actionability of MRD and also offers a clear example of the utility of MRD assessment in the clinic.

Minimal residual disease (MRD) refers to the small number of cancer cells that remain in a patient's body after treatment, causing no signs or symptoms and eventually leading to recurrence of the disease. The presence of residual disease is widely accepted by the medical community as a predictor of long-term outcomes following an initial course of cancer treatment. As therapies for ALL and other lymphoid cancers become more efficacious, there is a definitive need for more refined and sensitive tools to identify remaining cancer cells and track them over time.

"The expansion of the blinatumomab label to include patients with ALL who are MRD-positive serves a critically important unmet need for our patients. This marks the first FDA approval of a treatment for leukemia patients who are classified as being in remission but still have measurable disease after induction therapy and adds to the growing body of peer-reviewed data and clinical guidelines surrounding MRD," said Aaron Logan, Assistant Professor, Division of Hematology and Blood and Marrow Transplantation, UCSF. "MRD quantification has become an indispensable tool, helping physicians and patients make important treatment decisions. Access to a rigorously validated and widely available MRD test is vital in this context."

"We are thrilled for patients, the medical community and Amgen. The FDA approval of Amgen's BLINCYTO for MRD-positive ALL patients is groundbreaking, both because it represents the first-ever MRD-directed treatment, and because it affirms the clinical relevance of MRD negativity as an endpoint," said Chad Robins, co-founder and CEO of Adaptive. "Adaptive is committed to setting the standard for how minimal residual disease is measured in blood cancer, and we look forward to continuing our MRD-focused collaboration with Amgen."

About Minimal Residual Disease
Minimal residual disease (MRD) refers to the small number of cancer cells that remain in a patient's body after treatment, causing no signs or symptoms and eventually leading to recurrence of the disease. In lymphoid cancers such as ALL and multiple myeloma, MRD can be present in the bone marrow or blood at levels undetectable by conventional cytomorphological methods.

About Adaptive Biotechnologies®
Adaptive Biotechnologies is a pioneer and leader in combining high-throughput sequencing and expert bioinformatics to profile T-cell and B-cell receptors. Adaptive is bringing the accuracy and sensitivity of its immunosequencing platform into laboratories around the world to drive groundbreaking research in cancer and other immune-mediated diseases. Adaptive's mission is to translate immunosequencing discoveries into clinical diagnostics and therapeutics to improve patient care. For more information, please visit **adaptivebiotech.com**.

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