Adaptive Biotechnologies Announces a Collaboration With Sanofi to use Adaptive's clonoSEQ® Assay to Measure Minimal Residual Disease in Active and Future Isatuximab Multiple Myeloma Trials

May 29, 2018

SEATTLE, Wa., May 29, 2018. Adaptive Biotechnologies, the leader in combining Next Generation Sequencing (NGS) and expert bioinformatics to profile T- and B-cell receptors of the adaptive immune system, announced today that it entered into an agreement with Sanofi to utilize Adaptive's NGS-based clonoSEQ® Assay to assess minimal residual disease (MRD) status in response to isatuximab. This investigational anti-CD38 monoclonal antibody is in clinical development for the treatment of newly diagnosed, relapsed and/or refractory multiple myeloma (MM).

Through this collaboration, the parties will work together to evaluate the clinical value of monitoring MRD negativity in isatuximab-treated MM patients. Adaptive will be responsible for seeking regulatory approvals for and commercialization of the clonoSEQ Assay in MM for select geographies. Adaptive will receive upfront payments and potential future milestone payments. Financial terms of the agreement were not disclosed.

"Adaptive is thrilled to apply its technology to help determine the depth and duration of response to isatuximab in MM-treated patients," said Chad Robins, CEO and co-founder of Adaptive Biotechnologies. "We look forward to kicking off our collaboration and applying our validated, highly sensitive and quantitative clonoSEQ Assay to measure MRD status as a clinical endpoint in Sanofi's clinical trials."

The use of residual disease assessment to inform drug development has steadily increased in the past few years. Currently, there are three published meta-analyses[1, 2, 3] describing the utility of incorporating a highly sensitive MRD measurement to evaluate a patient's response to therapy. This collaboration is Adaptive's fourth collaboration with leading biopharmaceutical companies.

"MRD status is being incorporated as an important clinical endpoint to assess response to therapy in patients with multiple myeloma and other lymphoid malignancies," said Charles Sang, Adaptive's Senior Vice President, Diagnostics. "We are excited to work with Sanofi on its late-stage MM trials to help demonstrate the clinical utility of achieving MRD negativity in isatuximab-treated patients."

About Minimal/Measurable Residual Disease
Minimal/measurable residual disease (MRD) refers to cancer cells that remain in the body of a person with lymphoid cancer after treatment. These cells can be present at levels undetectable by traditional morphologic, microscopic examination of blood, bone marrow or a lymph node biopsy. Sensitive molecular technologies, such as next-generation sequencing utilized by the Adaptive Biotechnologies clonoSEQ Assay, are needed for reliable detection of MRD at levels below the limits of traditional assessment.

About the clonoSEQ® Assay
The Adaptive Biotechnologies clonoSEQ Assay enables physicians to utilize a molecular, NGS-based minimal/measureable residual disease (MRD) detection to inform clinical decisions in patients with lymphoid malignancies. The clonoSEQ Assay detects and quantifies DNA sequences found in malignant cells, which can be tracked in patients longitudinally on- and post-treatment. This robust assay provides consistent and accurate measurement of disease burden that allows physicians to assess response to therapy over time. Adaptive is seeking 510(K) marketing authorization from FDA for the clonoSEQ Assay. Currently clonoSEQ is not FDA cleared but is distributed as a CLIA certified service. Nothing in this release constitutes a recommendation to use clonoSEQ with respect to a particular drug therapy. This release may contain forward looking statements that are subject to risks and uncertainties including but not limited to the risk that approval or commercialization of products or services will be delayed or not obtained, and the risk that future milestones will not be achieved.

About Adaptive Biotechnologies
Adaptive Biotechnologies is the pioneer and leader in combining NGS and expert bioinformatics to profile T-cell and B-cell receptors. Adaptive is bringing the accuracy and sensitivity of its immunosequencing platform to researchers and clinicians around the world to drive groundbreaking research in cancer and other immune-mediated diseases. Adaptive also translates immunosequencing discoveries into clinical diagnostics and therapeutic development to improve patient care. For more information, please visit adaptivebiotech.com.

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1. Landgren O, et.al. *BMT*, 2016.
2. Munshi NC, et.al. *JAMA Oncol*, 2017.
3. Berry DA, et. al. *JAMA Oncol*, 2017.

Adaptive biotechnologies®

COLLABORATIONS