

Precision BioSciences Receives FDA Authorization to Initiate Clinical Study of Gene Edited Cancer Immunotherapy

Allows for the Initiation of Human Testing in Company's First Oncology Program

DURHAM, North Carolina, USA, November 27th, 2018 – Precision BioSciences and Servier today announced that the U.S. Food and Drug Administration (FDA) has accepted the Investigational New Drug (IND) application for PBCAR0191, an allogeneic anti-CD19 CAR T therapy for B-cell acute lymphoblastic leukemia (B-ALL) and non-Hodgkin lymphoma (NHL). Upon trial initiation, PBCAR0191 will be Precision's first clinical-stage product candidate.

"Our allogeneic CAR T program has exceeded all expectations, moving from concept to IND acceptance in under three years," said Matt Kane, Chief Executive Officer of Precision. "We are thrilled to have received authorization to initiate clinical studies for a therapy that we believe could be transformative for patients suffering with NHL and B-ALL."

Precision's PBCAR0191 is positioned to be the first gene-edited allogeneic CAR T product candidate in human clinical trials for NHL. Data provided to the FDA in connection with the IND submission included the results of in depth off target cutting analyses and evidence to support the elimination of graft versus host interactions. Manufacturing data were provided to the FDA in support of the scalability and reproducibility of the T cell genome editing production process. Precision is currently producing clinical trial material at full scale with its manufacturing partner.

A major development in the fight against cancer, T cells are engineered to carry a tumor-targeting chimeric antigen receptor (CAR) and have the potential to save the lives of many patients unresponsive to traditional chemotherapy and radiation regimens. Autologous CAR T therapies currently on the market rely on patient-derived T cells, which are extracted and individually manufactured for each patient using that patient's own cells, which involves a complex and lengthy process.

Precision's allogeneic CAR T product candidates utilize T cells derived from qualified donors, which are manufactured in large batches and cryopreserved for shipment, storage, and off-the-shelf administration. These allogeneic CAR T product candidates rely on Precision's ARCUS genome editing platform to remove the T cell receptor in order to prevent graft versus host disease without the need for donor-patient matching. ARCUS editing also enables targeted insertion of the CAR gene into a single, specific location in the T cell genome for more controlled, consistent expression.

About Precision BioSciences

Precision BioSciences is dedicated to improving life. Our mission is to cure genetic disease, overcome cancer, and feed the planet. We are striving to achieve this goal with ARCUS,

our therapeutic-grade, naturally-derived genome editing platform to help overcome life's greatest genetic challenges. For additional information, please visit www.precisionbiosciences.com.

About Servier

Servier is an international pharmaceutical company governed by a non-profit foundation, with its headquarters in France (Suresnes). With a strong international presence in 149 countries and a turnover of 4.152 billion euros in 2017, Servier employs 21,700 people worldwide. Entirely independent, the Group reinvests 25% of its turnover (excluding generic drugs) in research and development and uses all its profits for development. Corporate growth is driven by Servier's constant search for innovation in five areas of excellence: cardiovascular, immune-inflammatory and neuropsychiatric diseases, cancer and diabetes, as well as by its activities in high-quality generic drugs. Servier also offers eHealth solutions beyond drug development. For more information: www.servier.com.

About the Collaboration

Under their February 2016 partnership with Baxalta, now with Servier, Precision is solely responsible for early-stage research activities, manufacturing, and Phase 1 execution for PBCAR0191. Servier has the exclusive right to opt in for late-stage development and commercialization, and Precision has the right to participate in the development and commercialization of any licensed products resulting from the collaboration through a 50/50 co-development and co-promotion option in the United States.

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