Poseida Therapeutics Receives US FDA Orphan Drug Designation for P-BCMA-101 for the Treatment of Multiple Myeloma

SAN DIEGO, May 13, 2019 (GLOBE NEWSWIRE) -- Poseida Therapeutics Inc., a clinical-stage biopharmaceutical company leveraging proprietary non-viral gene engineering technologies to create life-saving therapeutics, today announced the United States Food and Drug Administration (FDA) has granted orphan drug designation to P-BCMA-101 for the treatment of relapsed and/or refractory multiple myeloma. P-BCMA-101 is an autologous CAR-T therapy developed using Poseida's piggyBac® platform technology. P-BCMA-101 is comprised of a high percentage of long-lived, self-renewing stem cell memory T cells targeting cancer cells expressing B-cell maturation antigen (BCMA).

"FDA orphan designation is an important regulatory milestone in the continued development and commercialization of P-BCMA-101," said Eric Ostertag, M.D., Ph.D., chief executive officer of Poseida. "P-BCMA-101 has demonstrated outstanding potency, with strikingly low rates of toxicity in our phase 1 clinical trial. In fact, the FDA has approved fully outpatient dosing in our Phase 2 trial starting in the second quarter of 2019."

Poseida's non-viral piggyBac DNA Modification System results in CAR-T product candidates with a high percentage of stem cell memory T cells (Tscm), the only T cell that is self-renewing and long-lived, leading to CAR-T products with improved efficacy, lower toxicity and potentially greater durability than earlier generation CAR-T therapies.

Orphan drug designation is granted by the FDA Office of Orphan Products Development to drugs and biologics which are intended for the treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S. Under the Orphan Drug Act, the FDA may provide grant funding toward clinical trial costs, tax advantages, FDA user-fee benefits and seven years of market exclusivity in the United States following marketing approval by the FDA.

Poseida has received grant funding from the California Institute for Regenerative Medicine to support the clinical development of P-BCMA-101.

About Poseida Therapeutics, Inc.
Poseida Therapeutics is a clinical-stage biotechnology company translating best-in-class gene engineering technologies into lifesaving treatments for patients with high unmet medical need. The company is developing a wholly-owned pipeline of autologous and allogeneic CAR-T product candidates, initially focused on the treatment of hematological malignancies and solid tumors, as well as gene therapies for orphan genetic diseases. Poseida has assembled a suite of industry-leading gene editing technologies, including the piggyBac® DNA Modification System, Cas-CLOVER™ and TAL-CLOVER™ site-specific nucleases and Footprint-Free® Gene Editing. For more information, visit www.poseida.com.

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