



## **Poseida Therapeutics Receives Regenerative Medicine Advanced Therapy (RMAT) Designation from FDA for P-BCMA-101**

SAN DIEGO, Nov. 05, 2018 (GLOBE NEWSWIRE) -- Poseida Therapeutics Inc., a clinical-stage biopharmaceutical company focused on leveraging proprietary next-generation, non-viral gene engineering technologies to create life-saving therapeutics, today announced the U.S. Food and Drug Administration (FDA) has granted a Regenerative Medicine Advanced Therapy (RMAT) designation to P-BCMA-101, Poseida's lead CAR-T therapeutic candidate currently in a Phase 1 clinical trial for the treatment of patients with relapsed/refractory multiple myeloma. RMAT designation includes all of the benefits of the Fast Track and Breakthrough Therapy designation programs, including early interactions with the FDA.

"P-BCMA-101 is the first anti-BCMA CAR-T therapy to receive RMAT designation from the FDA and underscores the urgent need for new treatment options for multiple myeloma," said Eric Ostertag, M.D., Ph.D., chief executive officer of Poseida Therapeutics. "Initial Phase 1 data presented at the CAR-TCR Summit earlier this year included encouraging response rates and safety data, including meaningful responses in a heavily pretreated population, with some patients reaching VGPR and stringent CR. We expect to have an additional data update by the end of the year and look forward to working closely with the FDA to expedite development of P-BCMA-101."

The RMAT designation is a program under the 21<sup>st</sup> Century Cures Act that is intended to expedite the development and review of regenerative medicines for the treatment of serious or life-threatening diseases and conditions. A regenerative medicine therapy is eligible for the designation if it is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product has the potential to address unmet medical needs for such a disease or condition.

RMAT designation includes all Breakthrough Therapy designation features, including early interactions to discuss any potential surrogate or intermediate endpoints. RMATs may be eligible for accelerated approval based on previously agreed-upon surrogate or intermediate endpoints that are reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites, as appropriate.

### **About P-BCMA-101**

P-BCMA-101 is an autologous CAR-T therapeutic candidate being developed to treat patients with relapsed/refractory multiple myeloma. P-BCMA-101 targets cells that express B cell maturation antigen, or BCMA, which is expressed on essentially all multiple myeloma cells. P-BCMA-101 is engineered with Poseida's non-viral piggyBac™ DNA Modification System, resulting in a high percentage of T stem cell memory cells. Preliminary results from the company's ongoing Phase 1 clinical trial suggest that P-BCMA-101 may have improved response rates with a favorable safety profile compared to published results from clinical trials of other CAR-T therapies at similar doses. Low to no levels of cytokine release syndrome or neurotoxicity have been seen. The Phase 1 study is funded in part by the California Institute for Regenerative Medicine.

### **About Poseida Therapeutics, Inc.**

Poseida Therapeutics is a clinical-stage biotechnology company leveraging proprietary next-generation non-viral, gene engineering technologies to create life-saving therapeutics 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. Poseida's product candidates are designed to address the limitations of other CAR-T therapies, including duration of response, the ability to treat solid tumors and safety concerns. P-BCMA-101 is Poseida's lead CAR-T therapy currently in Phase 1 clinical development for the treatment of relapsed/refractory multiple myeloma.

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