Poseida Therapeutics Receives Regenerative Medicine Advanced Therapy (RMAT) Designation from FDA for P-BCMA-ALLO1 to Treat Relapsed/Refractory Multiple Myeloma

FDA evaluated RMAT application based on positive clinical data from ongoing Phase 1 study of P-BCMA-ALLO1; new clinical data from the study will be presented at the 21st International Myeloma Society Annual Meeting this month

RMAT designation recognizes potential of P-BCMA-ALLO1 to address significant unmet needs of multiple myeloma patients and enables increased dialogue with FDA throughout the development process

SAN DIEGO, Sept. 16, 2024 /PRNewswire/ -- Poseida Therapeutics, Inc. (Nasdaq: PSTX), a clinical-stage allogeneic cell therapy and genetic medicines company advancing differentiated non-viral treatments for patients with cancer and rare diseases, today announced that the U.S. Food and Drug Administration (FDA) granted Regenerative Medicine Advanced Therapy (RMAT) designation to P-BCMA-ALLO1, an investigational stem cell memory T cell (T_{SCM})-based allogeneic CAR-T cell therapy in Phase 1/1b clinical development for the treatment of patients with relapsed/refractory multiple myeloma.

RMAT designation includes all the benefits of the Fast Track and Breakthrough Therapy designation programs, including early interactions with the FDA. Poseida's RMAT application was evaluated based on encouraging early data from its ongoing Phase 1 study of P-BCMA-ALLO1, which demonstrated P-BCMA-ALLO1's potential to offer promising efficacy, safety profile and rapid 'off-the-shelf' patient access.

"The RMAT designation for P-BCMA-ALLO1, our lead program, is based on impressive early clinical data from our ongoing Phase 1 study and further validates its potential to address the unmet needs of patients with relapsed/refractory multiple myeloma," said Kristin Yarema, Ph.D., president and chief executive officer of Poseida Therapeutics. "Importantly, our data has shown clinical responses in very sick, refractory patients, including those that have received prior BCMA-targeted therapies. With both RMAT and Orphan Drug designations for P-BCMA-ALLO1, we look forward to working closely with the FDA as we continue to advance this next-generation, off-the shelf allogeneic CAR-T therapy, including the recently initiated Phase 1b portion of the trial."

The Company will report new clinical data from the P-BCMA-ALLO1 Phase 1 study in an oral session at the 21st International Myeloma Society Annual Meeting, which is being held in Rio de Janeiro from September 25-28, 2024. Additional clinical updates are planned for the second half of 2024, subject to coordination with Roche, which has a strategic collaboration with Poseida covering multiple investigational allogeneic CAR-T therapies targeting blood cancers, including P-BCMA-ALLO1.

The RMAT designation is a program under the 21st Century Cures Act that is intended to expedite the development and review of regenerative medicine therapies for serious or life-threatening diseases or conditions. A regenerative medicine therapy is eligible for RMAT 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 regenerative medicine therapy has the potential to address unmet medical needs for such 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-ALLO1
P-BCMA-ALLO1 is an allogeneic CAR-T product candidate licensed to Roche targeting B-cell maturation antigen (BCMA) for the treatment of relapsed/refractory multiple myeloma. This allogeneic program includes a VH-based binder that targets BCMA and clinical data presented at ASH in December 2023 support the Company's belief that T stem cell (T_{SCM})-rich allogeneic CAR-Ts have the potential to offer effective, safe, and reliable treatment addressing unmet needs in multiple myeloma. The FDA has granted P-BCMA-ALLO1 Regenerative Medicine Advanced Therapy (RMAT) designation for adult patients with relapsed/refractory multiple myeloma after three or more prior lines of therapies including a proteasome inhibitor (PI), an immunomodulatory agent (IMiD), and anti-CD38 antibody in addition to Orphan Drug designation for multiple myeloma. Additional information about the Phase 1/1b study is available at www.clinicaltrials.gov using identifier: NCT04960579.

About Poseida Therapeutics, Inc.
Poseida Therapeutics is a clinical-stage biopharmaceutical company advancing differentiated allogeneic cell therapies and genetic medicines with the capacity to cure certain cancers and rare diseases. The Company's pipeline includes investigational allogeneic CAR-T cell therapies for both solid tumors and hematologic cancers as well as investigational in vivo genetic medicines that address patient populations with high unmet medical need. The Company's approach is based on its proprietary genetic editing platforms, including its non-viral piggyBac® DNA Delivery System, Cas-CLOVER™ Site-Specific Gene Editing System, Booster Molecule and nanoparticle gene delivery technologies, as well as in-house GMP cell therapy manufacturing. The Company has formed strategic collaborations with Roche and Astellas to unlock the promise of cell therapies for cancer patients. Learn more at www.poseida.com and connect with Poseida on X and LinkedIn.

Forward-Looking Statements
Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements regarding, among other things, expected plans with respect to clinical trials, including timing of regulatory submissions and approvals and clinical data updates; anticipated timelines and milestones with respect to the Company's development programs and manufacturing activities and capabilities; the potential capabilities and benefits of the Company's technology platforms and product candidates, including the efficacy and safety profile of such product candidates; the quote from Dr. Yarema; the potential benefits from receiving Regenerative Medicine Advanced Therapy designation for P-BCMA-ALLO1; and the Company's plans and strategy with respect to developing its technologies and product candidates. Because such statements are subject to risks and uncertainties,

actual results may differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon the Company's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, the Company's reliance on third parties for various aspects of its business; risks and uncertainties associated with development and regulatory approval of novel product candidates in the biopharmaceutical industry; the Company's ability to retain key scientific or management personnel; and the other risks described in the Company's filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

View original content to download multimedia:https://www.prnewswire.com/news-releases/poseida-therapeutics-receives-regenerative-medicine-advanced-therapy-rmat-designation-from-fda-for-p-bcma-allo1-to-treat-relapsedrefractory-multiple-myeloma-302248568.html

SOURCE Poseida Therapeutics, Inc.

Poseida Investor and Media Relations: Alex Chapman, Senior Vice President, IR & Corporate Communications, IR@poseida.com; Sarah Thailing, Senior Director, IR & Corporate Communications, PR@poseida.com