Poseida Therapeutics Announces FDA Orphan Drug Designation Granted to P-BCMA-ALLO1 for the Treatment of Multiple Myeloma

Data Describing Activity of P-BCMA-ALLO1 in BCMA-Experienced Patients to be Presented at Upcoming AACR Meeting

SAN DIEGO, March 13, 2024 /PRNewswire/ -- Poseida Therapeutics, Inc. (Nasdaq: PSTX), a clinical-stage cell and gene therapy company advancing a new class of treatments for patients with cancer and rare diseases, today announced the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for the treatment of multiple myeloma to P-BCMA-ALLO1, a novel BCMA-targeted allogeneic, T stem cell memory (T_{SCM})-rich chimeric antigen receptor (CAR)-T therapy candidate. The Company is investigating P-BCMA-ALLO1 in partnership with Roche for the treatment of relapsed/refractory multiple myeloma (RRMM).

"The Orphan Drug Designation for P-BCMA-ALLO1 underscores the high unmet medical need for a rapid and accessible off-the-shelf allogeneic CAR-T therapy for patients with multiple myeloma," said Kristin Yarema, Ph.D., President and Chief Executive Officer of the Company. "This designation further validates our belief that T_{SCM}-rich allogeneic CAR-T therapies may potentially offer the optimal combination of clinical results, on-demand availability, and high-volume production, while supporting broader access to CAR-T therapies. We look forward to continuing our work on the Phase 1 study of P-BCMA-ALLO1 and plan to share further clinical updates in 2024."

The Company is currently evaluating P-BCMA-ALLO1 in a Phase 1 clinical trial and recently shared positive early safety and preliminary efficacy data at the 65th American Society of Hematology (ASH) Annual Meeting and Exposition in December 2023. Data highlighted at the meeting showed that P-BCMA-ALLO1 was a well-tolerated off-the-shelf therapy with a favorable emerging safety profile, delivered to 100% of patients in the intent-to-treat population with no use of bridging chemotherapy or other anti-myeloma bridging therapies. Preliminary data presented at ASH also showed allogeneic T_{SCM}-rich CAR-T cells trafficking to bone marrow, differentiating to cell-killing effector T cells and persisting at least 6 weeks after treatment, which support the hypothesis of cell persistence at tumor-relevant sites.

The Company will present data on a subset of recently enrolled patients refractory to initial BCMA targeting therapy in a poster presentation at the American Association for Cancer Research (AACR) Annual Meeting in San Diego on April 8, 2024, 9:00 AM to 12:30 PM PT.

Subject to coordination with Roche, the Company plans to provide an additional clinical update on the P-BCMA-ALLO1 program at a scientific meeting in the second half of 2024.

The FDA's Orphan Drug Designation program provides orphan status to drugs or biologics intended for the prevention, diagnosis, or treatment of diseases that affect fewer than 200,000 people in the United States. Sponsors of medicines that are granted Orphan Drug Designation are entitled to certain incentives, including tax credits for qualified clinical trials, prescription drug user-fee exemptions, and potential seven-year marketing exclusivity upon FDA approval.

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_{SCM}-rich allogeneic CAR-Ts have the potential to offer effective, safe, and reliable treatment addressing unmet needs in multiple myeloma. Additional information about the Phase 1 study is available at www.clinicaltrials.gov using identifier: NCT04960579.

About Poseida Therapeutics, Inc.

Poseida Therapeutics is a clinical-stage biopharmaceutical company advancing differentiated cell and gene therapies with the capacity to cure certain cancers and rare diseases. The Company's pipeline includes allogeneic CAR-T cell therapy product candidates for both solid and liquid tumors as well as in vivo gene therapy product candidates that address patient populations with high unmet medical need. The Company's approach to cell and gene therapies 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 and hybrid gene delivery technologies as well as in-house GMP cell therapy manufacturing. The Company has formed a global strategic collaboration with Roche to unlock the promise of cell therapies for patients with hematological malignancies. 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 Company's ability to exploit and consummate additional business development opportunities; the Company's ability to attract and/or retain new and existing collaborators with relevant expertise and its expectations regarding the potential benefits to be derived from any such collaborations; potential benefits from receiving Orphan Drug 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; the fact that the Company will have limited control over the efforts and resources that Roche devotes to advancing development programs under its collaboration agreement and the Company may not receive the potential fees and payments under the collaboration agreement and the ability of Roche to early terminate the collaboration, such that the Company may not fully realize the benefits of the collaboration; 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.

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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