Poseida Therapeutics Presents New Phase 1 Data at AACR 2024 Supporting Potential of P-BCMA-ALLO1 Allogeneic CAR-T Therapy to Benefit Broad Range of Patients with Multiple Myeloma

- *Promising early data suggest patients with relapsed/refractory multiple myeloma who progressed after prior BCMA-targeted therapy achieved clinical responses with P-BCMA-ALLO1, which was well tolerated*
- *Following efforts to optimize allogeneic CAR-T therapy, Poseida is presenting a new data analysis underscoring the need for higher lymphodepletion chemotherapy doses when treating solid tumors vs. multiple myeloma*

SAN DIEGO, April 8, 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 new data from a subset of patients in an ongoing Phase 1 study of its lead program, P-BCMA-ALLO1. Results showed that three of the five (60%) patients with relapsed/refractory multiple myeloma who had progressed following BCMA-targeted therapy achieved clinical responses with P-BCMA-ALLO1. In addition, this investigational treatment was well-tolerated.

P-BCMA-ALLO1 is a novel investigational B-cell maturation antigen (BCMA)-targeted allogeneic, T stem cell memory (T_{SCM})-rich chimeric antigen receptor T-cell (CAR-T) therapy manufactured from healthy donor T-cells and available off-the-shelf. These new Phase 1 study subgroup data and a new data analysis of different lymphodepletion regimens in patients treated with P-BCMA-ALLO1 for multiple myeloma or P-MUC1C-ALLO1 for solid tumors are being presented today in a poster session at the American Association for Cancer Research (AACR) Annual Meeting 2024 in San Diego.

"Multiple myeloma remains incurable, and patients often relapse, despite initial high response rates with BCMA-targeted immunotherapies, including autologous CAR-T therapies," said Bhagirathbhai Dholaria, M.D., Associate Professor of Medicine (Hematology/Oncology) at the Vanderbilt-Ingram Cancer Center in Nashville, Tenn. "New treatment options are urgently needed for these patients, which is why I'm encouraged by these impressive Phase 1 subgroup results, which may be the first report of an allogeneic CAR-T therapy showing clinical activity in heavily pretreated patients whose myeloma has progressed after multiple BCMA-targeted immunotherapies."

"These new data build on the P-BCMA-ALLO1 data presented at ASH 2023, which demonstrated a 100% overall response rate in patients who had not been previously treated with a BCMA-targeted therapy. The new findings also provide additional evidence that our investigational, off-the-shelf allogeneic CAR-T therapy could be an appropriate treatment for a broader range of patients with multiple myeloma, including those with relapsed/refractory disease whose cancer progressed following prior BCMA-targeted therapy, representing the highest unmet need in this setting," said Syed Rizvi, M.D., Chief Medical Officer at Poseida. "In addition, we continue to explore the optimal lymphodepletion regimen for CAR-T in solid tumors and are directly applying these learnings to our P-MUC1C-ALLO1 trial with the goal of delivering the same benefits in solid tumors as we have seen in myeloma. We look forward to sharing more fulsome datasets on both our BCMA and MUC1-C programs in the second half of 2024."

New Phase 1 P-BCMA-ALLO1 Study Subgroup Data
The open-label, multicenter Phase 1 dose-escalation study in patients with relapsed/refractory multiple myeloma is assessing the safety and maximum tolerated dose of P-BCMA-ALLO1 (primary objective) and its anti-myeloma activity (secondary objective). Study participants were required to have received a prior proteasome inhibitor, immunomodulatory drug and anti-CD38 monoclonal antibody. Five study participants who had progressed on or following prior BCMA-targeting autologous CAR-T, T-cell engagers or both, and with ninety days post-P-BCMA-ALLO1 treatment follow-up, are presented in this poster.

Key findings from the subgroup analysis showed that P-BCMA-ALLO1 was well tolerated with no dose-limiting toxicities, graft vs. host disease, or Grade 3 or greater cytokine release syndrome (CRS) or immune effector cell neurotoxicity syndrome (ICANS). The overall response rate in patients receiving P-BCMA-ALLO1 was 60%, with all three patients who achieved a clinical response experiencing a very good partial response (VGPR). This included one patient who had previously received both teclistamab and an autologous CAR-T therapy and has maintained a response for more than four months.

New Data on Optimizing Lymphodepletion (LD) Regimen for Patients with Solid Tumors Treated with Investigational Allogeneic CAR-T Therapy
As patients with multiple myeloma receive more bone marrow suppressive treatments than those with solid tumors during their treatment journeys, this analysis evaluated the effect of increasing amounts of cyclophosphamide in LD regimens to optimize CAR-T pharmacokinetics.

The analysis compared various LD regimens in two early Phase 1 trials of Poseida's investigational allogeneic CAR-T cell therapies in patients with multiple myeloma and solid tumors. Results showed that patients with solid tumors may require higher cyclophosphamide doses to achieve adequate LD, which would provide a sufficient niche to support allogeneic CAR-T expansion.

Poster Presentation Details

Title	Poster #	Presenting Author	Session Title	Session Date/Time	Location
Clinical Activity of P-BCMA-ALLO1, a B-cell Maturation Antigen (BCMA) Targeted Allogeneic Chimeric Antigen Receptor T-cell (CAR-T) Therapy, in Relapsed Refractory Multiple Myeloma (RRMM) Patients Following Progression on Prior BCMA Targeting Therapy	CT071	Rajesh Belani, M.D., Clinical Development, Poseida Therapeutics	Phase I Clinical Trials 1	Monday, April 8, 9:00 a.m.-12:30 p.m. PT	Poster section 48, Poster board 21

Solid Tumor Patients Require Higher Cyclophosphamide Dose than Multiple Myeloma Patients to Achieve Adequate Lymphodepletion Necessary to Enable Allogeneic CAR-T Expansion	CT070	Sabrina Haag, Ph.D., Translational Medicine, Poseida Therapeutics	Phase I Clinical Trials 1	Monday, April 8, 9:00 a.m.-12:30 p.m. PT	Poster section 48, Poster board 20

About P-BCMA-ALLO1
P-BCMA-ALLO1 is an investigational allogeneic CAR-T therapy licensed to Roche that targets B-cell maturation antigen (BCMA) and is in Phase 1 clinical development for the treatment of patients with relapsed/refractory multiple myeloma. This allogeneic program includes a VH-based binder that targets BCMA. Phase 1 clinical data presented at ASH 2023 supports 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. The U.S. Food and Drug Administration granted Orphan Drug Designation to P-BCMA-ALLO1 for the treatment of multiple myeloma. Additional information about the Phase 1 study is available at www.clinicaltrials.gov (NCT04960579).

About P-MUC1C-ALLO1
P-MUC1C-ALLO1 is an investigational allogeneic CAR-T therapy in Phase 1 clinical development for multiple solid tumor indications. Poseida believes P-MUC1C-ALLO1 has the potential to treat a wide range of solid tumors derived from epithelial cells, such as breast, ovarian, colorectal, lung, pancreatic and renal cancers, as well as other cancers expressing a cancer-specific form of the Mucin 1 protein (MUC1-C). P-MUC1C-ALLO1 is designed to be fully allogeneic, with genetic edits to eliminate or reduce both host-vs-graft and graft-vs-host alloreactivity. Poseida has demonstrated the elimination of tumor cells to undetectable levels in preclinical models of both breast and ovarian cancer. Additional information about the Phase 1 study is available at www.clinicaltrials.gov (NCT05239143).

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, safety and reliability profile of such product candidates; the quotes from Drs. Dholaria and Rizvi; 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 interim data from the Company's clinical trials may change as more patient data become available and remain subject to audit and verification procedures that could result in material differences from the final data; the fact that subgroup data may differ from future results of the same study once additional data has been received; 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-presents-new-phase-1-data-at-aacr-2024-supporting-potential-of-p-bcma-allo1-allogeneic-car-t-therapy-to-benefit-broad-range-of-patients-with-multiple-myeloma-302110563.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