



Poseida Therapeutics Highlights Positive Interim Phase 1 Results for P-BCMA-ALLO1 and Preclinical Data for Dual CAR-T P-CD19CD20-ALLO1 at the 66th American Society of Hematology (ASH) Annual Meeting

Additional new profiling of patient responses from the optimized lymphodepletion arm (Arm C) show consistent P-BCMA-ALLO1 cellular expansion and persistence across subgroups

New preclinical data supports P-CD19CD20-ALLO1's strong anti-cancer profile and the ongoing Phase 1 clinical trial

Case study demonstrates reactivation of an autologous Poseida CAR-T therapy with a T-cell engager in patient with relapsed multiple myeloma, highlighting potential of T_{SCM}-based CAR-T therapies to deliver a strong anti-myeloma response with long-term remission and CAR-T cell persistence

SAN DIEGO, Dec. 9, 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, autoimmune and rare diseases, today will highlight interim clinical data from its Phase 1 trial of P-BCMA-ALLO1 in patients with relapsed/refractory multiple myeloma (RRMM), including new profiling of patient responses from Arm C, an optimized lymphodepletion arm. The P-BCMA-ALLO1 data are being presented, along with two additional Company poster presentations covering new preclinical data for P-CD19CD20-ALLO1 and a patient case study demonstrating the reactivation of a Poseida autologous CAR-T therapy with a T-cell engager, at the 66th ASH Annual Meeting and Exposition being held in San Diego on December 7-10, 2024.

P-BCMA-ALLO1 is an investigational non-viral, stem cell memory T cell (T_{SCM})-rich allogeneic CAR-T cell therapy in Phase 1/1b clinical development for the treatment of patients with RRMM. P-CD19CD20-ALLO1 is an investigational, non-viral T_{SCM}-rich allogeneic CAR-T cell therapy in Phase 1 clinical development for the treatment of patients with B-cell malignancies and is the Company's first dual CAR-T program. P-BCMA-ALLO1 and P-CD19CD20-ALLO1 are being developed in collaboration with Roche.

"We continue to gain confidence in the potential for P-BCMA-ALLO1 in multiple myeloma, including from the additional sub-analysis of the Phase 1 data presented at ASH," said Kristin Yarema, Ph.D., President and Chief Executive Officer of Poseida Therapeutics. "We believe the data to-date provide strong validation for our allogeneic cell therapy platform, laying the groundwork for us to extend our non-viral, T_{SCM}-rich approach and drive value with additional clinical programs. This includes P-CD19CD20-ALLO1, our first dual CAR-T supported by preclinical data presented at ASH, and with clinical data anticipated in 2025."

P-BCMA-ALLO1 Phase 1 Data

The poster presentation will highlight Phase 1 clinical data first presented at the 21st International Myeloma Society (IMS) Annual Meeting in September 2024. The data showed a 91% overall response rate (ORR) in Arm C (an optimized lymphodepletion arm), including a 100% ORR in B-cell maturation antigen (BCMA)-naïve patients, and an 86% ORR in those who had received at least one prior BCMA- and/or G protein-coupled receptor class C group 5 member D (GPRC5D)-targeting treatment modality, along with differentiated safety results with no dose-limiting toxicities, low rates of cytokine release syndrome (CRS) and immune effector cell neurotoxicity syndrome (ICANS), all Grade 2 or less, and no graft vs. host disease or Parkinsonism. No patients required anti-myeloma bridging therapy or prophylaxis with steroids or tocilizumab, and there was no invasive apheresis; an average manufacturing wait time, from treatment decision to clinical response, was only 3.5 weeks¹ (with a median time to response of 16 days post initial P-BCMA-ALLO1 therapy). The patients in this study had more advanced disease than the myeloma patients studied in clinical trials of approved autologous CAR-T therapies², and in the intent-to-treat population, 100% of patients were infused with P-BCMA-ALLO1.

New profiling of patient responses from Arm C are included in the ASH poster presentation. The data from this analysis show consistent P-BCMA-ALLO1 cellular expansion and persistence across different subgroups, including patients that are typically more challenging to treat. Key highlights suggest that P-BCMA-ALLO1:

- Cellular kinetics were not impacted by prior BCMA/GPRC5D-targeted therapy
- Expands and persists in patients with extramedullary disease (EMD)

P-CD19CD20-ALLO1 Preclinical Data

Preclinical data has demonstrated that P-CD19CD20-ALLO1 delivers high in vitro potency and strong in vivo antitumor activity for either CD19 or CD20 single-positive target cells, as well as double-positive targets. New preclinical data included in the poster presentation show that compared to CD19-single targeting or CD20-single targeting CAR-T cells, P-CD19CD20-ALLO1:

- Achieved higher and more durable killing of tumor cells over three rechallenges, even in the presence of only one tumor antigen
- Exhibited higher cytotoxicity
- Produced higher and more sustained levels of effector cytokines (IL-2, IFN- γ , sFasL, Granzyme A and Granulysin) that play an important role mediating the immune system response to cancers
- Showed higher in vivo antitumor efficacy than the CD19-single targeting CAR-T cells

The Company's P-CD19CD20-ALLO1 Phase 1 clinical trial is enrolling patients with selected B-cell malignancies, with initial clinical data anticipated in 2025.

CAR-T Reactivation with T-cell Engager Case Study

The case study highlights the reactivation of an autologous Poseida CAR-T therapy with a T-cell engager in a patient with relapsed multiple myeloma. The patient attained and remained in stringent complete response over 12 months after CAR-T reactivation. This case highlights the potential of Poseida's T_{SCM}-based CAR-T therapies to deliver a strong anti-myeloma response with long-term remission and CAR-T cell persistence. The

Company believes this is the first time that a T-cell engager has been seen to reactivate a CAR-T therapy.

ASH 2024 Poster Presentations

Title: Late Polyclonal P-BCMA-101 CAR-T Cell Re-expansion and Rapid Complete Response in a Patient with Relapsed Multiple Myeloma Treated with One Cycle of Talquetamab, More Than 3 Years After CAR-T Infusion

- **Presenting Author:** Anupama Kumar, M.D., Assistant Professor, Hematology, Blood & Marrow Transplant, and Cellular Therapy (HBC) Program, University of California, San Francisco (UCSF)
- **Session:** 704. Cellular Immunotherapies: Early Phase Clinical Trials and Toxicities: Poster I
- **Presentation Date/Time:** Saturday, December 7, 2024, 5:30-7:30 p.m. PT (8:30-10:30 p.m. ET)
- **Room:** Halls G-H, San Diego Convention Center
- **Abstract Number:** 2083

Title: P-CD19CD20-ALLO1: Potent Fully Allogeneic CAR-T Therapy Targeting CD19 and CD20 with Superior Efficacy Over Single-Target Products

- **Presenting Author:** Samy Jambon, Ph.D., Poseida Therapeutics
- **Session:** 702. CAR-T Cell Therapies: Basic and Translational: Poster III
- **Presentation Date/Time:** Monday, December 9, 2024, 6:00-8:00 p.m. PT (9:00-11:00 p.m. ET)
- **Room:** Halls G-H, San Diego Convention Center
- **Abstract Number:** 4805

Title: A Phase 1 Study of P-BCMA-ALLO1, a Non-viral, Allogeneic BCMA Directed CAR-T in Relapsed/Refractory Multiple Myeloma (RRMM): Results from Optimized Lymphodepletion Cohort

- **Presenting Author:** Caitlin Costello, M.D., Professor of Medicine, Director of Multiple Myeloma Program, Division of Blood and Marrow Transplant, Moores Cancer Center, University of California, San Diego (UCSD)
- **Session:** 704. Cellular Immunotherapies: Early Phase Clinical Trials and Toxicities: Poster III
- **Presentation Date/Time:** Monday, December 9, 2024, 6:00-8:00 p.m. PT (9:00-11:00 p.m. ET)
- **Room:** Halls G-H, San Diego Convention Center
- **Abstract Number:** 4828

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 interim clinical data presented at IMS in September 2024 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 Orphan Drug designation for multiple myeloma and 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, an immunomodulatory agent and an anti-CD38 antibody.

P-BCMA-ALLO1 is currently being evaluated in a Phase 1/1b trial in patients with multiple myeloma. Additional information about the trial is available at www.clinicaltrials.gov using identifier: NCT04960579.

About P-CD19CD20-ALLO1

P-CD19CD20-ALLO1 is an allogeneic CAR-T cell therapy product candidate being developed for relapsed or refractory B-cell malignancies in partnership with Roche. P-CD19CD20-ALLO1 expresses two fully functional CAR molecules to target cells that express either CD19 or CD20. The dual targeting approach employed in P-CD19CD20-ALLO1 aims to overcome the antigen escape limitations of CD19-only targeted CAR-T therapies by simultaneously targeting both CD19 and CD20. In addition to the dual targeting, P-CD19CD20-ALLO1 uses a novel CD19 binder that showed greater potency in in vivo preclinical models when compared to the canonical FMC63 Single-chain variable fragment (scFv) binder. P-CD19CD20-ALLO1 is an off-the-shelf CAR-T therapy for which patients do not have to undergo apheresis and wait for cells to be manufactured, which can potentially overcome the limitation of autologous CAR-T therapies associated with significant manufacturing times. P-CD19CD20-ALLO1 is being studied in a Phase 1 study in B-cell malignancies (www.clinicaltrials.gov using identifier: NCT06014762). Building on the transformative potential of the CAR-T modality beyond oncology, the Company has recently submitted investigational new drug (IND) applications to the U.S. Food and Drug Administration (FDA) to investigate this program's potential for patients with multiple sclerosis and systemic lupus erythematosus.

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. The Company's pipeline includes investigational allogeneic CAR-T cell therapies for hematologic cancers, autoimmune diseases, and solid tumors, 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 transposon-based 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 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; 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 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 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 Company's ongoing and planned clinical trials; risks and uncertainties associated with conducting clinical trials; competition in the Company's target markets; whether any of the Company's product candidates will be shown to be effective, safe or reliable; the Company's ability to finance continued operations; the fact that the Company will have limited control over the efforts and resources that Roche devotes to advancing development programs under the collaboration agreement with Roche; the fact that the Company may not receive the potential fees, reimbursements and payments under its collaboration agreement with Roche; 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 and uncertainties 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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¹ Based on interim data from Phase 1 P-BCMA-ALLO1 clinical trial announced in September 2024, Arms A and B.

² No head-to-head trial has been conducted evaluating P-BCMA-ALLO1 against other products included herein. Cross-trial data interpretation should be considered with caution as it is limited by differences in study population, study design, and other factors.

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