Poseida Therapeutics Highlights Recent Progress, Strategic Priorities and Anticipated 2024 Key Milestones

Reported positive early clinical data for allogeneic myeloma cell therapy P-BCMA-ALLO1 at ASH 2023 supporting potential of T_{SCM}-rich allogeneic CAR-T to offer a differentiated and compelling efficacy, safety, and reliability profile that could compete with autologous CAR-T

Plan to report clinical data updates for P-BCMA-ALLO1and P-MUC1C-ALLO1 allogeneic CAR-T programs at scientific meetings in 2024

Expect to dose first patient in the Phase 1 P-CD19CD20-ALLO1 trial in early 2024

Company to host Gene Therapy R&D Day April 17, 2024

SAN DIEGO, Jan. 4, 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 highlighted recent progress across the company's cell and gene therapy portfolio and provided updates on anticipated upcoming milestones.

"In 2023, we made significant progress in delivering on the promise of our pipeline of allogeneic cell therapies through both substantial manufacturing advancements and compelling clinical data. At the ASH Annual Meeting, we were thrilled to highlight the ability of P-BCMA-ALLO1, our T_{SCM}-rich CAR-T therapy for multiple myeloma, to offer a compelling emerging efficacy and safety profile that we believe will be competitive with autologous cell therapies and bispecific antibodies, and to treat patients without lengthy waiting times," said Kristin Yarema, Ph.D., President and Chief Executive Officer of the Company. "In parallel, we expanded our partnership with Roche, accelerating the expected timing of achievement and increasing the certainty of certain milestones as well as advancing programs at all stages in the Roche collaboration. Notably, we cleared the IND for P-CD19CD20-ALLO1, which we believe is the first known dual allogeneic CAR-T directed against CD19 and CD20. In our non-viral gene therapy portfolio, we are advancing P-FVIII-101 as a potentially durable treatment for Hemophilia A and believe that the recent preclinical data presented at ASH continue to support our liver-targeted non-viral delivery platform. Together with our strong financial position and bolstered by our robust business development and partnership activity, we believe we are well positioned for success in 2024."

"As we work to build on this momentum in 2024, we plan to report interim Phase 1 data in both our BCMA and MUC1C programs as well as dose the first patient in our allogeneic CD19CD20 dual CAR program targeting B-cell malignancies, which is partnered with Roche. We also expect to advance IND-enabling studies directed toward our wholly-owned allogeneic PSMA program in prostate cancer. In our gene therapy portfolio, we look forward to providing a comprehensive strategic update at our upcoming gene therapy-specific R&D Day in April, as we continue advancing our non-viral DNA delivery platform to unlock potential for genetic diseases. We believe we are entering a new era of cell and gene therapies, and I am thrilled to step into the role of President and CEO of Poseida at this transformative moment."

Program Highlights

Cell Therapy Programs

BCMA Program
P-BCMA-ALLO1 is a potential first-in-class allogeneic, T_{SCM}-rich CAR-T product candidate being developed to target B-cell maturation antigen (BCMA) for the treatment of relapsed/refractory multiple myeloma (R/R MM) in partnership with Roche. 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. There were no cases of GvHD or dose-limiting toxicities and low incidences of CRS and neurotoxicity observed (all ≤ Grade 2). The data showed an 82% overall response rate (ORR) and deep clinical responses, including stringent complete responses (sCRs) in MRD-negative patients, from the off-the-shelf, allogeneic BCMA-targeted CAR-T in heavily pretreated patients in study arms receiving adequate lymphodepletion. Of those patients, a 100% ORR was seen in patients who were not previously treated with a BCMA-targeted bispecific T cell-engaging antibody. The median time from study enrollment to start of lymphodepletion chemotherapy was 1 day and was 7 days to P-BCMA-ALLO1 infusion. Preliminary data show 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 supports the hypothesis of cell persistence at tumor-relevant sites. At the time of data cutoff, 8 of 9 responding patients were still in clinical response.

In 2024, Poseida plans to continue development of P-BCMA-ALLO1 in partnership with Roche. This includes continuing the strong enrollment in the Phase 1 study, refinement of dosing regimen for both cell dose and lymphodepletion chemotherapy, sharing additional details on clinical trial expansion strategies and continuing product supply efforts. The Company plans to present additional clinical data updates for P-BCMA-ALLO1 at scientific meetings in 2024, subject to coordination with Roche.

CD19CD20 Program
P-CD19CD20-ALLO1 is an allogeneic, T_{SCM}-rich CAR-T product being developed to target B-cell malignancies in partnership with Roche. P-CD19CD20-ALLO1 is the Company's first dual CAR program and contains two fully functional CAR molecules to target cells that express either CD19 or CD20 or both. The Company believes P-CD19CD20-ALLO1 is the first known dual allogeneic CAR-T directed against CD19 and CD20 to receive IND clearance from the FDA. The Company expects to dose the first patient in the Phase 1 trial of P-CD19CD20-ALLO1 for B-cell malignancies in early 2024 and provide a data update later in the year, subject to coordination with Roche.

MUC1C Program
P-MUC1C-ALLO1 is an allogeneic, T_{SCM}-rich CAR-T product candidate targeting the C-terminal domain of the mucin-1 protein (MUC1C), which is

prevalent in solid tumors of epithelial origin, including breast, ovarian, and multiple other cancers. The Company is currently evaluating P-MUC1C-ALLO1 in a Phase 1 clinical trial with a basket study design. Building on learnings from the allogeneic BCMA CAR-T program, the Company is evaluating multiple dosing strategies, including higher lymphodepletion, cell dose, and schedule in its MUC1C program. Poseida plans to provide a data update at a scientific meeting in the first half of 2024.

PSMA Program
P-PSMA-ALLO1 is an allogeneic CAR-T product candidate targeting prostate-specific membrane antigen, or PSMA, to treat prostate cancer. This allogeneic program utilizes VH-based binding technology, similar to the approach used in the Company's P-BCMA-ALLO1 program, but targeting PSMA. When compared to the previous autologous PSMA program that used a Centyrin binder, in preclinical models, enhanced anti-tumor activity was observed using this newer binder. Based upon progress and learnings from its autologous P-PSMA-101-001 clinical trial and across its allogenic platform, the Company plans to advance IND-enabling work for P-PSMA-ALLO1 in 2024.

Early Stage Research
The Company plans to continue early pipeline research activities and advance IND-enabling work for other allogeneic pipeline programs, including exploring opportunities in autoimmune disease.

Gene Therapy Programs

At its Gene Therapy R&D Day event in April 2024, the Company plans to share updates on its programs and outcomes from its strategic review process.

FVIII Program
The Company is advancing its P-FVIII-101 preclinical program, a fully non-viral liver-directed gene therapy combining Poseida's proprietary piggyBac® DNA Delivery System with nanoparticle delivery for the treatment of Hemophilia A. The Company recently presented preclinical data from this program at the ASH Annual Meeting in December 2023, demonstrating the capabilities of the piggyBac DNA insertion system and non-viral approach in providing stable Factor VIII transgene expression, along with the potential for redosing. The P-FVIII-101 program is among the programs advanced through the Company's former partnership with Takeda and Poseida received full rights back after Takeda's change in strategy away from gene therapy and rare disease.

OTC Program
P-OTC-101 is a liver-directed gene therapy for the treatment of urea cycle disease caused by congenital mutations in the ornithine transcarbamylase (OTC) gene. The Company is developing the P-OTC-101 program utilizing a hybrid delivery system (AAV+LNP) and working on an updated timeline for the program. P-OTC-101 received orphan drug designation from the FDA in July 2023.

PAH Program
P-PAH-101 is a liver-directed gene therapy for the treatment of Phenylketonuria (PKU), an inherited genetic disorder caused by mutations in the phenylalanine hydroxylase (PAH) gene resulting in a buildup of phenylalanine in the body. The Company is developing P-PAH-101 program utilizing a hybrid system (AAV+LNP) and is currently in preclinical development.

Other Business Highlights

Fully Operationalized Internal Manufacturing Capabilities
Poseida has made substantial advancements in its allogeneic cell therapy manufacturing platform and capabilities. In 2023, Poseida established a fully internal clinical manufacturing capability which is now supplying all GMP products for all of its clinical trials across three programs. In addition, the Company has achieved yield improvements through optimization of unit operations, as described at the CAR-TCR Summit in September 2023, capable of delivering cell yields supporting up to 100+ doses per manufacturing run depending upon cell dose.

In 2024, the Company plans to continue to invest in its allogeneic platform for T_{SCM}-rich CAR-T, including proprietary non-viral technologies, and will continue to refine and improve its manufacturing processes in ways that will potentially further increase product yield generally.

Partnerships and Collaborations
In August 2023 the Company announced a $50 million strategic investment by Astellas and granted Astellas certain strategic rights, further validating Poseida's suite of genetic engineering technologies and its allogeneic T cell platform.

Poseida continues to develop allogeneic CAR-T therapies targeting hematological malignancies in partnership with Roche. The Company announced in November 2023 that, based upon substantial progress in its P-BCMA-ALLO1 and P-CD19CD20-ALLO1 programs, certain payments as well as the expected timing of achievement of upcoming milestones in programs have been accelerated to reflect progress in the programs and better align with expected upcoming further clinical developments and manufacturing needs and timelines. As a result of this progress, the Company expects to receive certain payments sooner and/or with more certainty than originally anticipated.

The Company continues to explore potential strategic and business development options for its technology platforms and gene therapy programs, as well as other potential opportunities in cell therapy.

Poseida R&D Days
In recognition of its continued development and growth, and to highlight its proprietary platform technologies and preclinical research in 2024, the Company plans to hold two R&D Days focusing on gene therapy and cell therapy respectively.

Poseida will hold an R&D Day focusing on gene therapy on April 17, 2024, when the Company plans to provide an update on its strategic review of its gene therapy and gene editing programs, as well as updates on its pipeline and focus areas. An R&D Day focusing on cell therapy will be hosted in the second half of 2024.

Organization

Kristin Yarema, Ph.D., has been appointed to the Company's Board of Directors, effective January 1st, 2024.

Cash Position and Runway

As previously announced, Poseida expects that its cash, cash equivalents and short-term investments together with the remaining near-term milestones and other payments from Roche and Astellas will be sufficient to fund operations into the second half of 2025. This cash runway reflects financial prudence but has mainly been driven through business development and partnership activity, for which Poseida continues to be well positioned.

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 us 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 quotes from Dr. Yarema; estimates of the Company's cash balance, expenses, capital requirements, and any future revenue; the Company's ability to exploit and consummate additional business development opportunities, including with Roche and/or Astellas, and any anticipated impact on the Company's cash balance and cash runway; 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; 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.

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