Poseida Therapeutics Announces FDA Clearance of Investigational New Drug Application for P-CD19CD20-ALLO1, an Allogeneic Dual CAR-T Cell Therapy for B-Cell Malignancies

Believed to be the first FDA IND clearance of an allogeneic dual CAR-T therapy targeting CD19 and CD20

SAN DIEGO, July 5, 2023 /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 that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for P-CD19CD20-ALLO1, the Company's first allogeneic dual CAR-T cell product candidate, which targets both CD19 and CD20 antigens for the treatment of relapsed or refractory B-cell malignancies and is being developed in partnership with Roche.

"We are pleased to receive IND clearance for P-CD19CD20-ALLO1, our third fully allogeneic CAR-T cell product candidate and the second therapy in our partnership with Roche for hematological malignancies that will enter the clinic. We believe this represents the FDA's first known IND clearance of an allogeneic dual CAR-T therapy targeting CD19 and CD20," said Kristin Yarema, Ph.D., President, Cell Therapy at Poseida. "The dual-targeting approach leverages our proprietary non-viral piggyBac® DNA Delivery System, which enables expression of two fully functional CAR molecules into T cells from healthy donors for the treatment of B-cell malignancies that may have heterogeneous antigen expression. We believe that targeting both CD19 and CD20 has the potential to overcome the limitations of currently available CD19-directed CAR-T products where antigen escape has been observed as an important resistance mechanism. It has been estimated that up to 40% of cases where B-cell malignancies relapse or are refractory to CD19 targeting autologous CAR-T therapy may involve antigen escape. We look forward to dosing the first patients in this study."

P-CD19CD20-ALLO1 will be evaluated in a Phase 1 multi-center, open-label, dose-escalation study that will enroll up to 70 adult patients with relapsed or refractory B-cell malignancies. The study will evaluate the safety, tolerability, and preliminary efficacy of P-CD19CD20-ALLO1. After enrollment, patients will receive a chemotherapy-based lymphodepletion regimen followed by administration of P-CD19CD20-ALLO1 allogeneic CAR-T cells. With the P-CD19CD20-ALLO1 IND now cleared, the Company is actively focused on opening clinical sites.

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 the cells to be manufactured, which can potentially overcome the limitation of autologous CAR-T therapies associated with significant manufacturing times. P-CD19CD20-ALLO1 will be studied in multiple B-cell malignancies.

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 and nanoparticle and hybrid gene delivery technologies. The Company has formed a global strategic collaboration with Roche to unlock the promise of cell therapies for patients. Learn more at www.poseida.com and connect with us on Twitter 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; 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 such 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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