Poseida Therapeutics Announces FDA Clearance of Investigational New Drug Application for P-MUC1C-ALLO1, a Fully Allogeneic CAR-T Targeting Multiple Solid Tumors

SAN DIEGO, Dec. 20, 2021 /PRNewswire/ -- Poseida Therapeutics, Inc. (Nasdaq: PSTX), a clinical-stage biopharmaceutical company utilizing proprietary genetic engineering platform technologies to create cell and gene therapeutics with the capacity to cure, today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for P-MUC1C-ALLO1, the Company's allogeneic CAR-T product candidate targeting multiple solid tumor indications.

Poseida announces FDA clearance of IND for P-MUC1C-ALLO1, a fully #allogeneic CAR-T targeting multiple solid tumors.

"We are excited to begin the P-MUC1C-ALLO1 trial, an evaluation of a fully allogeneic CAR-T product candidate with the potential to treat a wide range of solid tumors, including breast, ovarian and other cancers," said Eric Ostertag, M.D., Ph.D., Chief Executive Officer of Poseida Therapeutics. "The genetic edits in P-MUC1C-ALLO1 have been shown to reduce or fully eliminate alloreactivity, and our proprietary manufacturing process, which includes our booster molecule, has the potential to treat many patients from a single manufacturing run. We look forward to beginning this trial and to presenting initial clinical data in 2022."

P-MUC1C-ALLO1 is the Company's second fully allogeneic CAR-T product candidate to receive IND clearance in 2021 following P-BCMA-ALLO1 for the treatment of relapsed/refractory multiple myeloma. P-MUC1C-ALLO1 is the first product candidate to be produced out of the Company's new GMP facility, an internal pilot manufacturing plant located at its San Diego headquarters.

P-MUC1C-ALLO1 will be evaluated in a Phase 1 multi-center, open-label, dose escalation study in adults with locally advanced or metastatic epithelial-derived solid tumors refractory to standard of care therapy, or those deemed ineligible or refused another existing treatment option. The study will evaluate the safety, tolerability, and preliminary efficacy of P-MUC1C-ALLO1 and will follow a 3+3 design of dose-escalating cohorts. After a subject enrolls, P-MUC1C-ALLO1 allogeneic CAR-T cells will be administered, following a standard chemotherapy-based conditioning regimen. The study protocol allows for exploration of additional dosing regimens, including re-dosing once initial safety has been established.

About P-MUC1C-ALLO1
P-MUC1C-ALLO1 is an allogeneic CAR-T product candidate in preclinical development for multiple solid tumor indications. P-MUC1C-ALLO1 has the potential to treat a wide range of solid tumors derived from epithelial cells, such as breast, colorectal, lung, ovarian, pancreatic and renal cancers, as well as other cancers expressing a cancer-specific form of the Mucin 1 protein, or MUC1C. 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 triple-negative breast and ovarian cancer.

About Poseida Therapeutics, Inc.
Poseida Therapeutics is a clinical-stage biopharmaceutical company dedicated to utilizing our proprietary genetic engineering platform technologies to create next generation cell and gene therapeutics with the capacity to cure. We have discovered and are developing a broad portfolio of product candidates in a variety of indications based on our core proprietary platforms, including our non-viral piggyBac® DNA Delivery System, Cas-CLOVER™ Site-specific Gene Editing System and nanoparticle- and AAV-based gene delivery technologies. Our core platform technologies have utility, either alone or in combination, across many cell and gene therapeutic modalities and enable us to engineer our portfolio of product candidates that are designed to overcome the primary limitations of current generation cell and gene therapeutics. To learn more, visit 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, the potential benefits of Poseida's technology platforms and product candidates, Poseida's plans and strategy with respect to developing its technologies and product candidates, and anticipated timelines and milestones with respect to Poseida's development programs and manufacturing activities. 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 Poseida'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, risks and uncertainties associated with development and regulatory approval of novel product candidates in the biopharmaceutical industry and the other risks described in Poseida'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. Poseida 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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