Poseida Therapeutics Announces FDA Clearance of Investigational New Drug Application for P-BCMA-ALLO1, an Allogeneic CAR-T Candidate for Relapsed/Refractory Multiple Myeloma

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SAN DIEGO, Aug. 30, 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-BCMA-ALLO1, the Company's first fully allogeneic CAR-T product candidate for patients with relapsed/refractory multiple myeloma.

"We view a fully allogeneic CAR-T product candidate comprised of a high-percentage of desirable stem cell memory T cells (Tscm) as the 'holy grail' of cell therapy in oncology," said Eric Ostertag, M.D., Ph.D., Chief Executive Officer of Poseida Therapeutics. "P-BCMA-ALLO1 has a very high percentage of Tscm cells with the potential to demonstrate safety in line with our prior P-BCMA-101 autologous approach, allowing for fully-outpatient dosing. The increase in Tscm and a switch to an improved binder also gives P-BCMA-ALLO1 the potential for even better efficacy."

"Notably, Poseida's propriety booster molecule technology gives us the ability to produce up to hundreds of doses of P-BCMA-ALLO1 from a single manufacturing run, thereby dramatically reducing cost and further increasing accessibility for patients who desperately need better and safer cell therapies," Ostertag continued.

With the P-BCMA-ALLO1 IND now cleared, the Company is actively focused on opening clinical sites with the intention to begin dosing later this year. P-BCMA-ALLO1-101 is a Phase 1 study comprised of open-label, dose escalation, multiple cohorts of allogeneic T stem cell memory (Tscm) CAR-T cells in subjects with relapsed/refractory multiple myeloma. This Phase 1 study follows a 3+3 design of dose-escalating cohorts. After a subject enrolls, allogeneic CAR-T cells will be administered as a single dose, following a standard chemotherapy-based conditioning regimen. Treated subjects will undergo serial measurements of safety, tolerability, and response. The study protocol allows for exploration of additional dosing regimens, including re-dosing, once initial safety has been established.

About P-BCMA-ALLO1
P-BCMA-ALLO1 is Poseida's first fully allogeneic product candidate targeting B-cell maturation antigen (BCMA) for the treatment of relapsed/refractory multiple myeloma. In in vitro and in vivo preclinical studies, P-BCMA-ALLO1 showed effective, targeted cancer cell killing and cytokine secretion, with similar or superior performance in anti-tumor efficacy compared to an autologous CAR-T therapy, P-BCMA-101. Inclusion of a proprietary "booster molecule" in the allogeneic manufacturing process further improved expansion of gene-edited cells and enabled production of hundreds of patient doses from a single manufacturing run, thereby reducing the manufacturing cost per dose into the same range as that of a monoclonal antibody.

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 Modification 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 wholly-owned 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 the clinical data presented, the potential benefits of Poseida's technology platforms and product candidates and Poseida'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 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, the fact that future clinical results could be inconsistent with results observed to date 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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SOURCE Poseida Therapeutics, Inc.

Marcy Graham, VP, Corporate Affairs, Poseida Therapeutics, Inc., 858-779-3108, mgraham@poseida.com; Sarah Thailing, Director, Corporate Communications and IR, Poseida Therapeutics, Inc., 858-605-3717, sthailing@poseida.com