Poseida Therapeutics, Inc.

Item 8.01 Other Events

On August 17, 2020, Poseida Therapeutics, Inc. (the "Company") announced that following notification to the U.S. Food and Drug Administration (FDA) of a pause in enrollment pursuant to the protocol to investigate a patient death, it has received communication from the FDA that the Company's Phase 1 clinical trial for P-PSMA-101 in metastatic castrate resistant prostate cancer has been placed on clinical hold.

The patient in question had metastatic castrate-resistant prostate cancer, had failed treatment with multiple anti-cancer agents and was treated with P-PSMA-101 in late July. Through the first 7 days post-treatment, the patient had normal lab results and no clinical symptoms indicating an adverse event. The patient missed both his Day 10 and Day 14 follow up visits, but during this time developed symptoms that subsequently lead to hospitalization and he died of hepatic failure at Day 19 post-treatment. Although the direct cause of the hepatic failure has not yet been confirmed, the patient developed symptoms consistent with macrophage activation syndrome (MAS). MAS is a serious and potentially fatal overactivation of the immune system which has been associated with CAR-T therapies, but can have other causes such as infection and autoimmune disease. The patient also developed blurred vision which was diagnosed as uveitis. The clinical investigator has assessed the SAE as possibly related to P-PSMA-101 pending further investigation. To date, there have been no other serious adverse events of decreased vision, uveitis, MAS, or hepatic failure reported in study P-PSMA-101-001. There has also been no cytokine release syndrome or neurotoxicity reported to date.

The Company's assessment of the event and evaluation of next steps is ongoing, including assessment of protocol changes, if any, as indicated by the findings. The Company is awaiting a formal response from the FDA and is preparing recommendations designed to allow resumption of the clinical trial. Once the FDA's questions are answered and a plan submitted, the FDA then has 30 days to notify the Company if the clinical study of P-PSMA-101 may be resumed.

Forward-Looking Statements

Statements contained in this report 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, our plans and strategy with respect to developing our technologies and product candidates, including with respect to potential timing and plans of our on-going clinical trial of P-PSMA-101. These forward-looking statements are based upon our 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 clinical development of and regulatory decisions with respect to P-PSMA-101 and our other product candidates, as well as the other risks described in our filings with the Securities and Exchange Commission. All forward-looking statements contained in this report speak only as of the date on which they were made. We undertake 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.

A copy of Poseida's Form 8-K is available to view here:
https://sec.report/Document/0001193125-20-222442/

ENDS