Beam Therapeutics Announces FDA Clinical Hold on BEAM-201 IND Application

August 1, 2022

CAMBRIDGE, Mass., Aug. 01, 2022 (GLOBE NEWSWIRE) -- Beam Therapeutics Inc. (Nasdaq: BEAM), a biotechnology company developing precision genetic medicines through base editing, today announced that on Friday, July 29, 2022, the company was informed via e-mail communication from the U.S. Food and Drug Administration (FDA) that the BEAM-201 Investigational New Drug (IND) application for the treatment of relapsed/refractory T-cell acute lymphoblastic leukemia (T-ALL)/T cell lymphoblastic lymphoma (T-LL) has been placed on clinical hold. BEAM-201 is a potent and specific anti-CD7, multiplex-edited, allogeneic chimeric antigen receptor T cell (CAR-T) development candidate. The BEAM-201 IND was submitted at the end of June. The FDA indicated they will provide an official clinical hold letter to Beam within 30 days. Beam plans to provide additional updates pending discussion with the FDA.

About Beam Therapeutics
Beam Therapeutics (Nasdaq: BEAM) is a biotechnology company committed to establishing the leading, fully integrated platform for precision genetic medicines. To achieve this vision, Beam has assembled a platform that includes a suite of gene editing and delivery technologies and is in the process of building internal manufacturing capabilities. Beam's suite of gene editing technologies is anchored by base editing, a proprietary technology that is designed to enable precise, predictable and efficient single base changes, at targeted genomic sequences, without making double-stranded breaks in the DNA. This has the potential to enable a wide range of potential therapeutic editing strategies that Beam is using to advance a diversified portfolio of base editing programs. Beam is a values-driven organization committed to its people, cutting-edge science, and a vision of providing life-long cures to patients suffering from serious diseases.

Cautionary Note Regarding Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Investors are cautioned not to place undue reliance on these forward-looking statements, including, but not limited to, statements related to: the FDA's communication plans related to the clinical hold on the BEAM-201 IND; our plans and expectations for discussions with the FDA and the outcomes from the discussions; and the therapeutic applications and potential of our technology, including with respect to our ability to develop life-long, curative, precision genetic medicines for patients through base editing. Each forward-looking statement is subject to important risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement, including, without limitation, risks and uncertainties related to: our ability to develop, obtain regulatory approval for, and commercialize our product candidates, which may take longer or cost more than planned; our ability to raise additional funding, which may not be available; our ability to obtain, maintain and enforce patent and other intellectual property protection for our product candidates; the potential impact of the COVID-19 pandemic; the uncertainty that our product candidates, including BEAM-201, will receive regulatory approval necessary to initiate human clinical studies; uncertainty in the FDA's plans to communicate and discuss the clinical hold on the BEAM-201 IND with us and the risk that those discussions may be delayed; the uncertainty in the outcome of our discussions with the FDA regarding the clinical hold on the BEAM-201 IND; that preclinical testing of our product candidates and preliminary or interim data from preclinical studies and clinical trials may not be predictive of the results or success of ongoing or later clinical trials; that enrollment of our clinical trials may take longer than expected; that our product candidates may experience manufacturing or supply interruptions or failures; risks related to competitive products; and the other risks and uncertainties identified under the headings "Risk Factors Summary" and "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2021, under the heading "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, and in any subsequent filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by applicable law.

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