Beam Therapeutics Announces FDA Has Lifted the Clinical Hold on the Investigational New Drug Application for BEAM-201

December 2, 2022

CAMBRIDGE, Mass., Dec. 02, 2022 (GLOBE NEWSWIRE) -- Beam Therapeutics Inc. (Nasdaq: BEAM), a biotechnology company developing precision genetic medicines through base editing, today announced the U.S. Food and Drug Administration (FDA) has lifted the clinical hold and cleared the Investigational New Drug (IND) application for BEAM-201 for the treatment of relapsed/refractory T-cell acute lymphoblastic leukemia (T-ALL)/T-cell lymphoblastic lymphoma (T-LL). BEAM-201 is a potent and specific anti-CD7, multiplex-edited, allogeneic chimeric antigen receptor T-cell development candidate.

“The FDA’s clearance of our IND for BEAM-201 is an exciting moment for Beam and for the field of gene editing, as it represents the first IND clearance for a multiplex-base edited investigational drug,” said John Evans, chief executive officer of Beam. “We believe the future of cell therapy involves high levels of cell engineering, enabled by multiplex base editing technology. Combining four unique edits with high efficiency, BEAM-201 has the potential to make a substantial impact for patients diagnosed with these challenging T-cell cancers, who lack innovative, new treatment options for their disease. We’re pleased that this clearance allows us to bring this novel medicine into human clinical trials, and we look forward to providing updates on next steps for the program in 2023.”

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 commencement of clinical trials for BEAM-201; the therapeutic applications and potential of our technology, including with respect to relapsed/refractory T-ALL/T-LL; and 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, including its impact on the global supply chain; the uncertainty that our product candidates will receive regulatory approval necessary to initiate human clinical studies; 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 and initiation 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, in our Quarterly Report on Form 10-Q for the quarter ended September 30, 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.

This press release contains hyperlinks to information that is not deemed to be incorporated by reference in this press release.

Contacts:

Investors:
Chelcie Lister
THRUST Strategic Communications
chelcie@thrustsc.com

Media:
Dan Budwick
1AB
dan@1abmedia.com