LogicBio Therapeutics Receives FDA Fast Track Designation for LB-001 for the Treatment of Methylmalonic Acidemia (MMA)

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Fast Track designation facilitates development of new therapies that treat serious conditions and fulfill unmet needs for patients

LEXINGTON, Mass., Nov. 04, 2020 (GLOBE NEWSWIRE) -- LogicBio Therapeutics, Inc. (Nasdaq:LOGC) (LogicBio), a company dedicated to extending the reach of genetic medicine with pioneering targeted delivery platforms, announced today the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to its clinical candidate, LB-001 for the treatment methylmalonic acidemia (MMA). According to the FDA, the purpose of Fast Track designation is to get important new drugs to patients earlier by facilitating the development, and expediting the review, of drugs to treat serious conditions and fill an unmet medical need.

Commenting on the announcement, Daniel Gruskin, M.D., Senior Vice President, Head of Clinical Development of LogicBio, said, “We are pleased the FDA has granted Fast Track designation to LB-001 in recognition of the importance of our efforts to bring a durable treatment to the children suffering from MMA. With Fast Track status, we plan to continue to work closely with the FDA to fully utilize the opportunities presented by this designation to make LB-001 available to patients as quickly as possible.”

About Fast Track Designation

The FDA’s Fast Track designation is a process designed to expedite or facilitate the review of product candidates to treat serious conditions and fill an unmet medical need. Fast Track designation allows for early and frequent communication with the FDA throughout the entire drug development and review process. It may also allow for priority or rolling review of a company’s Biologics License Application (BLA).

About LogicBio Therapeutics

LogicBio Therapeutics is dedicated to extending the reach of genetic medicine with pioneering targeted delivery platforms. LogicBio’s proprietary genome editing technology platform, GeneRide, enables the site-specific integration of a therapeutic transgene without nucleases or exogenous promoters by harnessing the native process of homologous recombination. LogicBio has received FDA clearance for the first-in-human clinical trial of LB-001, a wholly owned genome editing program leveraging GeneRide for the treatment of methylmalonic acidemia. Patient enrollment is expected to begin in early 2021. In addition, LogicBio has a collaboration with Takeda to research and develop LB-301, an investigational therapy leveraging GeneRide for the treatment of the rare pediatric disease Crigler-Najjar syndrome.

LogicBio is also developing a Next Generation Capsid platform for use in gene editing and gene therapies. Data presented have shown that the capsids deliver highly efficient functional transduction of human hepatocytes with improved manufacturability with low levels of pre-existing neutralizing antibodies in human samples. Top-tier capsid candidates from this effort demonstrated significant improvements over benchmark AAVs currently in clinical development. LogicBio is developing these highly potent vectors for internal development candidates and potentially for business development collaborations.

LogicBio is headquartered in Lexington, Mass. For more information, please visit www.logicbio.com.

Forward Looking Statements

This press release contains “forward-looking” statements within the meaning of the federal securities laws, including those related to the timing, progress and results of the Company’s research and development activities, including those related to LB-001, and the significance and benefits of receiving the FDA’s Fast Track designation for LB-001 in MMA. These are not statements of historical facts and are based on management’s beliefs and assumptions and on information currently available. They are subject to risks and uncertainties that could cause the actual results and the implementation of the Company’s plans to vary materially, including the risks associated with the initiation, cost, timing, progress and results of the Company’s current and future research and development activities and preclinical studies and potential future clinical trials. In particular, the impact of the COVID-19 pandemic on the Company’s ability to progress with its research, development, manufacturing and regulatory efforts, including the Company’s plans to initiate, advance and complete its Phase 1/2 clinical trial for LB-001 in MMA, and the value of and market for the Company’s common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States and in other countries, and the effectiveness of actions taken globally to contain and treat the disease. These risks are discussed in the Company’s filings with the U.S. Securities and Exchange Commission (SEC), including, without limitation, the Company’s Annual Report on Form 10-K filed on March 16, 2020 with the SEC, the Company’s Quarterly Report on Form 10-Q filed on May 11, 2020, and the Company’s subsequent Quarterly Reports on Form 10-Q and other filings with the SEC. Except as required by law, the Company assumes no obligation to update these forward-looking statements publicly, even if new information becomes available in the future.

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