Omega Therapeutics Announces Submission of Investigational New Drug Application for OTX-2002, an Omega Epigenomic Controller, for MYC Driven Hepatocellular Carcinoma

June 15, 2022

Investigational New Drug Application Submitted by Omega Represents the First Epigenomic Controller in a New Class of Programmable mRNA Therapeutics

CAMBRIDGE, Mass., June 15, 2022 /PRNewswire/ -- Omega Therapeutics, Inc. (Nasdaq: OMGA) ("Omega") today announced the submission of an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for the Company's lead product candidate, OTX-2002, for the treatment of hepatocellular carcinoma (HCC). OTX-2002, an Omega Epigenomic Controller, is designed to downregulate c-Myc (MYC) expression pre-transcriptionally through epigenetic modulation while potentially overcoming MYC autoregulation.

"This is an important milestone for our Company, an IND achieved in approximately 26 months since we started working on the early constructs in discovery which culminated in OTX-2002. We are excited that this represents the first of many anticipated IND applications and the transition of the company to its next stage," said Mahesh Karande, President and Chief Executive Officer of Omega Therapeutics. "This also marks a milestone regulatory submission for the first epigenomic controller, a new class of programmable mRNA therapeutics enabled by our OMEGA platform. We believe our approach to engineering epigenomic controllers has immense potential across a broad range of diseases, including HCC, which carries a 5-year survival rate of only 10%. We look forward to advancing OTX-2002 into the clinic and bringing it one step closer to patients in need."

The Company plans to initiate a Phase 1 clinical trial in the U.S. to evaluate OTX-2002, following FDA clearance.

About OTX-2002

OTX-2002 is a first-in-class Omega Epigenomic Controller™ in development for the treatment of HCC. OTX-2002 is a mRNA therapeutic delivered via lipid nanoparticles (LNPs) and is designed to downregulate c-Myc (MYC) expression pre-transcriptionally through epigenetic modulation while potentially overcoming MYC autoregulation. The MYC oncogene is associated with aggressive disease in up to ~70% of patients with HCC. An IND application has been submitted to the FDA.

About Omega Therapeutics

Omega Therapeutics, founded by Flagship Pioneering, is a development-stage biotechnology company pioneering the first systematic approach to use mRNA therapeutics as a new class of programmable epigenetic medicines. The company's OMEGA Epigenomic Programming™ platform harnesses the power of epigenetics, the mechanism that controls gene expression and every aspect of an organism's life from cell genesis, growth, and differentiation to cell death. Using a suite of technologies, paired with Omega's process of systematic, rational, and integrative drug design, the deterministic OMEGA platform enables control of fundamental epigenetic processes to correct the root cause of disease by returning aberrant gene expression to a normal range without altering native nucleic acid sequences. Omega's modular and programmable mRNA medicines, Omega Epigenomic Controllers™, target specific epigenomic loci within insulated genomic domains, EpiZips™, from amongst thousands of unique, mapped, and validated genome-wide DNA-sequences, with high specificity to durably tune single or multiple genes to treat and cure diseases through Precision Genomic Control™. Omega is currently advancing a broad pipeline of development candidates spanning a range of disease areas, including oncology, regenerative medicine, multigenic diseases including immunology, and select monogenic diseases, including alopecia.

For more information, visit omegatherapeutics.com, or follow us on Twitter and LinkedIn

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding future IND applications; the immense potential of our approach to engineering epigenomic controllers across a broad range of diseases; plans to initiate a Phase 1 clinical trial in the U.S. to evaluate OTX-2002; the potential of the OMEGA platform to engineer programmable epigenetic mRNA therapeutics that successfully regulate gene expression by targeting insulated genomic domains; expectations surrounding the potential of our product candidates, including OTX-2002; and expectations regarding our pipeline, including trial design, initiation of preclinical studies and advancement of multiple preclinical development programs in oncology, immunology, regenerative medicine, and select monogenic diseases. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the novel technology on which our product candidates are based makes it difficult to predict the time and cost of preclinical and clinical development and subsequently obtaining regulatory approval, if at all; the substantial development and regulatory risks associated with epigenomic controller machines due to the novel and unprecedented nature of this new category of medicines; our limited operating history; the incurrence of significant losses and the fact that we expect to continue to incur significant additional losses for the foreseeable future; our need for substantial additional financing; our investments in research and development efforts that further enhance the OMEGA platform, and their impact on our results; uncertainty regarding preclinical development, especially for a new class of medicines such as epigenomic controllers; the fact that our product candidates may be associated with serious adverse events, undesirable side effects or have other properties that could halt their regulatory development, prevent their regulatory approval, limit their

commercial potential, or result in significant negative consequences; the impact of increased demand for the manufacture of mRNA and LNP based vaccines to treat COVID-19 on our development plans; difficulties manufacturing the novel technology on which our OEC candidates are based; our ability to adapt to rapid and significant technological change; our reliance on third parties for the manufacture of materials; our ability to successfully acquire and establish our own manufacturing facilities and infrastructure; our reliance on a limited number of suppliers for lipid excipients used in our product candidates; our ability to advance our product candidates to clinical development; and our ability to obtain, maintain, enforce and adequately protect our intellectual property rights. These and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 and our other filings with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

Contacts

Media contact:
Jason Braco
LifeSci Communications
646.751.4361
jbraco@lifescicomms.com

Investor contact:
Kevin Murphy
Argot Partners
212.600.1902
ArgotOmega@argotpartners.com

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