Omega Therapeutics Announces FDA Clearance of IND Application for OTX-2002, First Omega Epigenomic Controller, for MYC Driven Hepatocellular Carcinoma

July 14, 2022

- *Represents First Ever Epigenomic Controller, a New Class of Programmable mRNA Therapeutics, to Receive IND Clearance*
- *Phase 1/2 Clinical Trial Expected to Launch in 2H'22 and Will Evaluate the Safety and Preliminary Antitumor Activity of OTX-2002*

CAMBRIDGE, Mass., July 14, 2022 /PRNewswire/ -- Omega Therapeutics, Inc. (Nasdaq: OMGA) ("Omega"), today announced that it has received clearance of its Investigational New Drug (IND) application from the U.S. Food and Drug Administration (FDA) to initiate a Phase 1/2, first-in-human, clinical study of OTX-2002 for the treatment of hepatocellular carcinoma (HCC). OTX-2002, an Omega Epigenomic Controller (OEC), is designed to downregulate c-Myc (MYC) expression pre-transcriptionally through epigenetic modulation while potentially overcoming MYC autoregulation.

"We are thrilled to obtain clearance to advance OTX-2002 into the clinic and are excited about the prospects of what this new class of medicines may mean for patients in need," said Mahesh Karande, President and Chief Executive Officer of Omega Therapeutics. "This is an important milestone for our company, representing our first program to receive FDA clearance to enter the clinic and the first ever clinical trial to evaluate an epigenomic controller. This new class of programmable mRNA therapeutics leverages our groundbreaking science and has broad potential applicability in many therapeutic areas."

About OTX-2002

OTX-2002 is a first-in-class Omega Epigenomic Controller™ in development for the treatment of HCC. OTX-2002 is an mRNA therapeutic delivered via lipid nanoparticles (LNPs) and is designed to downregulate 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 for OTX-2002 has been cleared by the FDA.

About Omega Therapeutics

Omega Therapeutics, founded by Flagship Pioneering, a clinical-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 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 our product candidate pipeline, including efficacy, trial design, regulatory submissions, approvals and timing thereof, the launch of a clinical trial of OTX-2002 and timing thereof, and the filing of future IND applications and timing thereof. 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.

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