Omega Therapeutics Announces Clinical Supply Agreement to Evaluate the Combination of OTX-2002 and Atezolizumab in Hepatocellular Carcinoma

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CAMBRIDGE, Mass., March 30, 2023 (GLOBE NEWSWIRE) -- Omega Therapeutics, Inc. (Nasdaq: OMGA) (“Omega”), a clinical-stage biotechnology company pioneering the development of a new class of programmable epigenetic mRNA medicines, today announced a clinical supply agreement with Roche to evaluate OTX-2002, its lead candidate in development for the treatment of MYC-driven hepatocellular carcinoma (HCC), in combination with Roche’s anti-PD-L1 therapy, atezolizumab, as part of Omega’s Phase 1/2 MYCHELANGELO™ I clinical trial.

“This agreement with Roche represents continued execution of our clinical trial strategy and the next step toward realizing the transformative potential of OTX-2002, a first-in-class epigenomic controller designed to pre-transcriptionally downregulate the MYC oncogene, a historically undruggable target,” said Mahesh Karande, President and Chief Executive Officer of Omega Therapeutics. “In preclinical studies, OTX-2002 demonstrated synergistic antitumor activity with existing standard of care therapies for HCC, including anti-PD-1 and anti-PD-L1 immune checkpoint inhibitors, with minimal impact on safety and tolerability. Through the combination of two orthogonal treatments, OTX-2002 and atezolizumab, a leading anti-PD-L1 therapy, we aim to simultaneously disrupt multiple drivers of cancer progression with the goal of improving treatment outcomes. With Roche’s support and partnership, we look forward to assessing the ability of this novel combination approach to enhance antitumor immune response in patients with advanced HCC.”

The ongoing Phase 1/2 MYCHELANGELO I trial is designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary antitumor activity of OTX-2002 as a monotherapy (Part 1) and in combination with standard of care therapies (Part 2), in patients with relapsed or refractory HCC and other solid tumor types known for association with the MYC oncogene. Preliminary data from the Phase 1 monotherapy dose escalation portion of the study are anticipated in 2023.

Under the terms of this agreement, Roche will supply atezolizumab and Omega will evaluate the combination as part of the overall conduct of the trial.

About OTX-2002
OTX-2002 is a first-in-class Omega Epigenomic Controller™ in development for the treatment of hepatocellular carcinoma (HCC). OTX-2002 is a programmable epigenetic mRNA therapeutic delivered via lipid nanoparticles (LNPs) and is designed to downregulate MYC expression pre-transcriptionally through epigenetic modulation while potentially overcoming MYC autoregulation. MYC is a master transcription factor that regulates cell proliferation, differentiation and apoptosis and plays a significant role in more than 50% of all human cancers. OTX-2002 is currently being evaluated in the Phase 1/2 MYCHELANGELO™ I trial in patients with relapsed or refractory HCC and other solid tumor types known for association with the MYC oncogene; visit clinicaltrials.gov (NCT05497453) for more details.

About Omega Therapeutics
Omega Therapeutics, founded by Flagship Pioneering, is a clinical-stage biotechnology company pioneering the development of a new class of programmable epigenetic mRNA medicines. The Company's OMEGA 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™(OECs), 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 unprecedented precision epigenomic control. Omega’s approach enables pre-transcriptional control of most human genes including historically undruggable, intractable, and difficult to treat targets. Omega’s pipeline of OEC candidates spans a range of disease areas, including oncology, regenerative medicine, multigenic diseases including immunology, and select monogenic diseases.

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 the terms and success of the agreement with Roche, the timing and design of our Phase 1/2 MYCHELANGELO™ I clinical trial and the timing of preliminary data therefrom; 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 controllers 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; potential delays in and unforeseen costs arising from our clinical trials; 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 Annual Report on Form 10-K for the year ended December 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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