# Omega Therapeutics Presents New Preclinical Data Supporting the First Epigenomic Controller, OTX-2002, as a Potential Therapeutic Approach in Hepatocellular Carcinoma at the ESMO 2022 World Congress on Gastrointestinal Cancer

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- *Treatment with epigenomic controller, OTX-2002, resulted in robust in vivo efficacy in xenograft tumor models*
- *OTX-2002 successfully achieved pre-transcriptional downregulation of hepatocyte MYC gene expression in non-human primates*
- *Clinical potential of OTX-2002 as a monotherapy or in combination with existing standard-of-care therapies, including immune checkpoint inhibitors*
- *IND filed by the company to advance OTX-2002 into the clinic*

CAMBRIDGE, Mass., June 30, 2022 /PRNewswire/ -- Omega Therapeutics, Inc. (Nasdaq: OMGA) (Omega), a development-stage biotechnology company pioneering the first systematic approach to use mRNA therapeutics as a new class of programmable epigenetic medicines by leveraging its OMEGA Epigenomic Programming™ platform, announces the presentation of new preclinical data on its lead product candidate, OTX-2002, to regulate expression of the c-Myc (MYC) oncogene through epigenetic modulation in multiple models of hepatocellular carcinoma (HCC) in a poster presentation at the European Society of Medical Oncology (ESMO) 2022 World Congress on Gastrointestinal (GI) Cancer, taking place in Barcelona, Spain, June 29 – July 2, 2022.

"We are proud to present these new data and add to the wealth of evidence supporting the potential of OTX-2002 as a new treatment option for patients suffering from HCC," said Thomas McCauley, Ph.D., Omega's Chief Scientific Officer. "In addition to providing strong evidence of OTX-2002's activity in the most translationally relevant species to human, non-human primates, the data support its potential as a monotherapy as well as its ability to synergize with existing treatment options. We believe epigenomic programming offers a promising avenue to precisely target previously undruggable genes, like MYC, that overcomes the compensatory mechanisms that have hindered previous modalities. We have recently filed an IND with the FDA for OTX-2002 and look forward to continuing to advance towards the clinic in service of patients."

## Key findings:

- In non-human primates, treatment with OTX-2002 resulted in durable reduction of MYC mRNA levels in liver consistent with previous in vitro and in vivo studies
- OTX-2002 treatment decreased MYC mRNA and protein levels and cell viability in multiple HCC cell lines, while sparing normal cells
- OTX-2002 significantly reduced tumor growth in HCC xenografts models
- OTX-2002 treatment is associated with decreased expression of the immune checkpoint factor PD-L1 in HCC cells, suggesting a potential role for combination therapy with immune checkpoint inhibitors
- Combining OTX-2002 with existing standard of care therapies for HCC resulted in further reduction of cell viability and tumor burden in both in vitro and in vivo HCC models, respectively
- OTX-2002 treatment demonstrated synergistic activity with AKT inhibition in HCC cells, highlighting additional possible combination approaches

The poster can be viewed on the Omega website at https://omegatherapeutics.com/our-science/#publications-research

## 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 for the treatment of HCC 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 our participation in upcoming events and presentations and expectations regarding our business strategy, OTX-2002 and product candidate pipeline, including efficacy, trial design, regulatory submissions, approvals and timing thereof, and the initiation of preclinical studies and advancement of multiple preclinical development programs. 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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