



Omega Therapeutics Presents Preclinical Data on OTX-2002, First-in-Class Epigenomic Controller, as Potential Treatment for Hepatocellular Carcinoma at the AACR Annual Meeting 2022

April 8, 2022

- OTX-2002 suppresses c-Myc gene expression resulting in a loss of cancer cell viability *in vitro* and reduces tumor growth in *in vivo* xenograft models
- Data support the potential of the OMEGA Epigenomic Programming™ platform to engineer programmable epigenetic mRNA therapeutics that successfully regulate gene expression
- Robust data support filing of Investigational New Drug application in the first half of 2022 and positions the OTX-2002 program for further development

CAMBRIDGE, Mass., April 8, 2022 /PRNewswire/ -- Omega Therapeutics (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, will present preclinical data highlighting the potential of its lead Omega Epigenomic Controller™, OTX-2002, to regulate overexpression of the c-Myc (MYC) oncogene in models of hepatocellular carcinoma (HCC) in a poster presentation at the American Association for Cancer Research (AACR) Annual Meeting 2022, taking place in New Orleans, Louisiana, April 8-13, 2022.

"Despite its essential role in a broad range of cancers, MYC has remained undruggable to date," said Thomas McCauley, Ph.D., Chief Scientific Officer of Omega Therapeutics. "However, we believe that targeting the MYC gene pre-transcriptionally within its Insulated Genomic Domain (IGD), and epigenetically tuning it using our epigenomic controller, could overcome the challenges that have limited previous technologies including small molecules, antisense oligos and siRNA. We believe that these data strongly support OTX-2002's ability to tune and restore MYC expression to a normal range and demonstrate the broader potential of our Epigenomic Programming platform to tackle previously intractable diseases. We are excited to continue advancing OTX-2002 into clinical trials and look forward to filing an Investigational New Drug application in the first half of this year."

Key findings

- A single dose of OTX-2002 induced durable changes in the epigenetic profile of the MYC gene
- OTX-2002 reduced MYC mRNA expression and protein levels over approximately 2 weeks *in vitro*
- Downregulation of MYC in multiple HCC cell lines resulted in significant loss in viability of MYC-addicted cancer cells while sparing normal cells
- In murine xenograft HCC models, OTX-2002 significantly reduced tumor growth and was well-tolerated

Cumulatively, these data support the filing of an Investigational New Drug application with the U.S. Food and Drug Administration for the clinical development of OTX-2002 in the first half of 2022.

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 hepatocellular carcinoma (HCC). OTX-2002 is designed to modulate levels of c-MYC (MYC) expression by utilizing targeted mRNA-expressed proteins to mediate epigenetic regulation while potentially overcoming MYC autoregulation. The MYC oncogene is associated with aggressive disease in up to ~70% of patients with HCC. Omega is currently evaluating OTX-2002 in Investigational New Drug (IND)-enabling studies.

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 epigenetic 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.

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 expectations surrounding the potential of our product candidates, including our lead OEC candidate OTX-2002; and our plans to present preclinical data on OTX-2002 and file an Investigational New Drug application for it in the first half of 2022. 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 Annual Report on Form 10-K for the period ended December 31, 2021, 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/Brendan Burns
Argot Partners
212.600.1902
ArgotOmega@argotpartners.com



 View original content to download multimedia: <https://www.prnewswire.com/news-releases/omega-therapeutics-presents-preclinical-data-on-otx-2002-first-in-class-epigenomic-controller-as-potential-treatment-for-hepatocellular-carcinoma-at-the-aacr-annual-meeting-2022-301521033.html>

SOURCE Omega Therapeutics