



Phio Pharmaceuticals Announces Regulatory Clearance of Clinical Trial With PH-762 and AgonOx's Tumor Infiltrating Lymphocytes (AGX148) to Treat Solid Tumors

January 6, 2023

MARLBOROUGH, Mass., Jan. 6, 2023 /PRNewswire/ -- Phio Pharmaceuticals Corp. (Nasdaq: PHIO) today announced their clinical development partner, AgonOx, Inc. has received confirmation from the FDA that their planned Phase 1 clinical trial in patients with advanced solid tumors may proceed. The initial Phase 1 clinical trial is designed to assess safety and to study the potential for an enhanced therapeutic benefit from the administration of Phio's PH-762 treated "double positive" (DP) CD8 tumor infiltrating lymphocyte (TIL) in patients with melanoma and other advanced solid tumors.

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Phio is a clinical stage biotechnology company whose proprietary INTASYL™ RNAi technology is designed to make immune cells more effective in killing tumor cells. Phio's PH-762 is an INTASYL compound that reduces the expression of PD-1, a protein that inhibits T cells' ability to kill cancer cells. By decreasing PD-1 expression, the T cells have increased capacity to kill cancer cells.

AgonOx, in collaboration with the Earle A. Chiles Research Institute, a division of Providence Cancer Institute of Oregon, has shown that DP CD8 T cells sorted from human solid tumors (AGX148) are highly enriched for tumor-reactivity leading to increased tumor killing when compared to the other CD8 tumor infiltrating lymphocyte (TIL) subsets.

Preclinical data from in-vitro studies using autologous human tumor cells demonstrated that treating AGX148 with Phio's PH-762 increased by two-fold their tumor killing activity. The trial will be conducted at Providence under the leadership of Dr. Weinberg and Principal Investigator Brendan Curti, MD, Medical Oncologist and Robert W. Franz Endowed Chair for Clinical Research.

"We're pleased to have reached this important milestone in our collaboration with AgonOx and Providence Cancer Institute to develop improved cell therapies for cancer patients," said Robert Bitterman, Phio's Principal Executive Officer and Executive Chairman.

"This bench to bedside research has the potential to help patients with solid malignancies and this is the first step to bringing this therapy to patients," said Andrew Weinberg, PhD, Founder and Chief Scientific Officer at AgonOx, Inc. and Research Scientist/Judy Hartmann Endowed Chair at Providence.

About AgonOx, Inc.

AgonOx, Inc. is a privately held, Portland, OR-based biotechnology company that spun out of the Earle A. Chiles Research Institute at the Providence Cancer Institute, Portland, OR. The company is developing a pipeline of novel immune-based cell therapies and immunotherapy drugs targeting key regulators of the immune response to cancer. For additional information, visit the company's website, www.agonox.com.

About Providence Cancer Institute of Oregon

Providence Cancer Institute, a part of Providence St. Joseph Health, offers the latest in cancer services, including diagnostic, treatment, prevention, education, support and internationally renowned research. Providence Cancer Institute is home to the Earle A. Chiles Research Institute, a world-class research facility located within the Robert W. Franz Cancer Center in Portland, Oregon, and is a recognized leader in the field of cancer immunotherapy since 1993. Investigators lead more than 400 active clinical trials in key areas such as cancers of the breast, colon, prostate, lung, esophagus, liver and pancreas, head and neck, ovary, skin and blood. Learn more at Providence.org/ORcancerinstitute.

About Phio Pharmaceuticals

Phio Pharmaceuticals Corp. (Nasdaq: PHIO) is a clinical stage biotechnology company whose proprietary INTASYL™ RNAi technology is designed to make immune cells more effective in killing tumor cells. INTASYL is the only self-delivering RNAi technology focused on immuno-oncology therapeutics. INTASYL drugs precisely target specific proteins that reduce the body's ability to fight cancer, without the need for specialized formulations or drug delivery systems.

For additional information, visit the Company's website, www.phiopharma.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as "intends," "believes," "anticipates," "indicates," "plans," "expects," "suggests," "may," "would," "should," "potential," "designed to," "will," "ongoing," "estimate," "forecast," "target," "predict," "could" and similar references, although not all forward-looking statements contain these words. Forward-looking statements are neither historical facts nor assurances of future performance and include statements regarding the anticipated timing of our PH-762 Phase 1 clinical trial and the anticipated results of such clinical trial. These statements are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results may differ materially from those indicated in the forward-looking statements as a result of a number of important factors, including, but not limited to, the impact to our business and operations by the ongoing coronavirus pandemic, military conflict between Ukraine and Russia, inflationary pressures, rising interest

rates, recession fears, the development of our product candidates, results from our preclinical and clinical activities, our ability to execute on business strategies, our ability to develop our product candidates with collaboration partners, and the success of any such collaborations, the timeline and duration for advancing our product candidates into clinical development, the timing or likelihood of regulatory filings and approvals, the success of our efforts to commercialize our product candidates if approved, our ability to manufacture and supply our product candidates for clinical activities, and for commercial use if approved, the scope of protection we are able to establish and maintain for intellectual property rights covering our technology platform, our ability to obtain future financing, market and other conditions and those identified in our Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q under the caption "Risk Factors" and in other filings the Company periodically makes with the SEC. Readers are urged to review these risk factors and to not act in reliance on any forward-looking statements, as actual results may differ from those contemplated by our forward-looking statements. Phio does not undertake to update forward-looking statements to reflect a change in its views, events or circumstances that occur after the date of this release, except as required by law.

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