Phio Pharmaceuticals Announces Positive DMC Recommendation and Continued Enrollment of Advanced Melanoma Study Without Modification

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MARLBOROUGH, Mass., Feb. 10, 2023 /PRNewswire/ -- Phio Pharmaceuticals Corp. (Nasdaq: PHIO), a clinical stage biotechnology company whose proprietary INTASYL™ RNAi platform technology is designed to make immune cells more effective in killing tumor cells, today announced that an independent Data Monitoring Committee (DMC) completed its prespecified review of interim safety data in the Company's Phase 1b clinical trial of PH-762 for the treatment of advanced melanoma. The trial is ongoing at the Gustave Roussy Institute (Villejuif, France), one of the largest cancer centers in Europe. PH-762 is an INTASYL compound that reduces the expression of cell death Protein 1 (PD-1), a protein that inhibits T cells' ability to kill cancer cells. Decreasing the expression of PD-1 increases the capacity of T cells to kill cancer cells.

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Following completion of the treatment period through excision of the tumor, safety data from the initial cohort of three subjects in the Phase 1 trial was evaluated by the DMC. The safety data review disclosed no dose-limiting toxicity, and no drug-related severe adverse events or serious adverse events, and the DMC recommended proceeding to the enrollment of the subsequent dose cohort, as intended per the study protocol.

"We are pleased with the recommendation of the DMC as a reflection of the favorable safety and tolerability profile of PH-762 to date, and will continue to obtain additional safety data as well as evidence of pharmacologic effect as we develop PH-762 for advanced cutaneous tumors," said Robert Bitterman, Phio's Principal Executive Officer and Executive Chairman.

In addition to the Phase 1b study in France, Phio expects to commence a US Phase 1b clinical trial focusing on the treatment of cutaneous squamous cell carcinoma (cSCC) and other selected cutaneous malignancies, early in the 2nd half of 2023.

About the Phase 1b Trial in Advanced Melanoma

The Phase 1b trial is an open-label, dose escalation trial that is expected to enroll up to 21 patients with advanced melanoma. PH-762 will be administered as a neoadjuvant monotherapy intratumorally once a week, for a total of four injections, across five dose levels which are normalized to tumor volume. Dosing will be followed by tumoral excision after an additional two weeks. The primary study objectives are: to evaluate the safety and tolerability, and pharmacokinetics of PH-762; to determine the potential immunologic and pathologic tumor responses; and to determine the recommended dose for later clinical studies. Tumor changes will be evaluated per RECIST criteria, adapted for use with intratumoral therapy, and by pathological response.

About INTASYL

INTASYL compounds are chemically modified siRNAs that provide efficient, spontaneous cellular uptake and potent, long lasting intracellular activity, targeting a broad range of cell types and tissues. 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. INTASYL has demonstrated preclinical efficacy in both Direct-to-Tumor and Adoptive Cell Therapy (ACT) applications.

In comparison to biologics and cell and gene therapies, INTASYL has a favorable pre-clinical toxicity and safety profile, and a streamlined chemical synthesis that reduces costs and offers substantial dosing convenience to the prescriber and patient. INTASYL is the only self-delivering RNA interference (RNAi) technology focused on immuno-oncology therapeutics.

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 timing of clinical studies and results and the potential for INTASYL therapeutics to treat cancer. 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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