Phio Pharmaceuticals Presents Study Outline of Its First Clinical Trial with PH-762 for Advanced Melanoma at the 2022 ASCO Annual Meeting

June 6, 2022

MARLBOROUGH, Mass., June 6, 2022 /PRNewswire/ -- Phio Pharmaceuticals Corp. (Nasdaq: PHIO), a clinical stage biotechnology company developing the next generation of therapeutics based on its proprietary self-delivering RNAi (INTASYL™) therapeutic platform, today presented a trial-in-progress poster describing the study outline of its Phase 1b clinical trial of PH-762, a self-delivering RNAi targeting PD-1, for the treatment of advanced melanoma at the 2022 American Society of Clinical Oncology (ASCO) annual meeting, which is being held June 3-7, 2022 in Chicago, IL.

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Immunotherapy with antibodies targeting immune checkpoints, such as PD-1, has shown significant benefit in late stage melanoma patients. However, further improvements in therapeutic options are still needed. Treatment given as a first step prior to surgery, or neoadjuvant treatment, and local intratumoral (IT) injection are two alternative approaches for improving the outcome of immunotherapy for melanoma patients.

"We are pleased to share the details for the ongoing clinical trial of our lead product, PH-762. As the first-in-human study for an INTASYL immunotherapy compound, the initiation of this study earlier this year marks an important milestone for our broader pipeline and platform," said Dr. Simon Fricker, Phio's VP of Research and Development. "Neoadjuvant therapy may stimulate significant responses that appear to be associated with a decrease in the risk of relapse after surgery. As there is currently no neoadjuvant standard of care for resectable advanced melanoma patients, neoadjuvant treatment with PH-762 provides an alternative therapeutic option to treat these patients."

IT administration of PH-762 to the tumor can stimulate a local immune response in the tumor microenvironment by silencing PD-1 and generating an immune response in distant untreated tumors. Studies conducted by the Company have shown potent silencing of PD-1 and a robust, dose-dependent inhibition of tumor growth. Further, IT injection of PH-762 also has the potential to minimize systemic effects and off-target toxicity, which has been seen with the use of antibodies.

The poster presented at ASCO outlines the design of the Phase 1b study with PH-762 for the treatment of patients with advanced melanoma. The clinical study is being conducted at the Gustave Roussy Institute, one of the largest cancer centers in Europe. The purpose of this study is three-fold: to evaluate the safety and pharmacokinetics of neoadjuvant use of PH-762 administered by IT injection in subjects with resectable advanced melanoma; to determine the recommended Phase 2 dose; and to determine the potential immunologic and pathologic tumor responses. Study treatment will feature a dose escalation of once weekly IT injections of PH-762 for four weeks prior to surgical excision of tumor lesion(s) after treatment with PH-762. Up to five dose levels will be tested in a serial fashion in cohorts of three or more subjects. A Bayesian optimal interval (BOIN) design will be employed to evaluate escalating doses of PH-762 to determine the maximum tolerated dose level and the dose of PH-762 will be normalized to tumor volume to ensure an equivalent local dose (tumor tissue concentration). Tumor changes will be evaluated per RECIST criteria, adapted for use with IT therapy, and by pathological response.

The poster being presented at ASCO, titled, "*A First-in-Human, Phase 1b Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Anti-Tumor Activity of Neoadjuvant Use of PH-762 Administered Intratumorally in Subjects with Advanced Melanoma*" will be made available on the "Investors – Events and Presentations" section of the Company's website (click here).

About PH-762

PH-762 activates immune cells to better recognize and kill cancer cells. It does so by reducing the expression of PD-1, a clinically validated target for immunotherapy. PD-1 is expressed by T cells and prevents them from killing cancer cells. When PH-762 reduces PD-1 expression, the "brakes" on the immune system are released and activates the T cells to kill the cancer cells. PH-762 is being developed as a standalone drug therapy with local IT administration to a tumor. In addition, it is also being developed as a critical component of cellular immunotherapy, more specifically to improve tumor cell killing capability of adoptively transferred tumor infiltrating lymphocyte (TIL) therapy.

About Phio Pharmaceuticals Corp.

Phio Pharmaceuticals Corp. (Nasdaq: PHIO) is a clinical stage biotechnology company developing the next generation of immuno-oncology therapeutics based on its self-delivering RNAi (INTASYL™) therapeutic platform. The Company's efforts are focused on silencing tumor-induced suppression of the immune system through its proprietary INTASYL platform with utility in immune cells and the tumor microenvironment. Our goal is to develop powerful INTASYL therapeutic compounds that can weaponize immune effector cells to overcome tumor immune escape, thereby providing patients a powerful new treatment option that goes beyond current treatment modalities. 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. 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, 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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