

Phio Pharmaceuticals Announces Agreement with U.S. cGMP Manufacturing Source for Drug Product, PH-762

A Critical Next Step in Advancing Phio's PH-762 Program to Treat Cutaneous Carcinomas

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[Phio Pharmaceuticals Corp. \(NASDAQ:](#)

[PHIO\)](#) is a clinical-stage siRNA

biopharmaceutical company

developing therapeutics using its proprietary INTASYL® gene silencing

technology to eliminate cancer. Phio

announced today that it has entered into a cGMP drug product manufacturing services

agreement with a U.S. manufacturer for clinical supply for future clinical trials. The company will manufacture Phio's lead compound PH-762 for both clinical trial and commercial supply.

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It's a pleasure to partner with an organization known for its quality and expertise in drug product manufacturing services. We value the strategic advantages of working with a U.S.-based organization.”

Robert Bitterman, President and CEO of Phio

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“It is a pleasure to partner with an organization known for its quality and expertise in drug product manufacturing services,” said Mr. Robert Bitterman, Phio's President and CEO. “Further, we value the strategic advantages of working with a U.S. based organization.”

Recent Company Highlights

Phio's lead clinical candidate, PH-762, is being evaluated as

an intratumoral therapy for cutaneous carcinomas. In its Phase 1b trial, Phio has reported that 22 patients completed treatment across five dose-escalation cohorts, with no dose-limiting toxicities or serious adverse events. The Company has also reported a pathological response rate in cSCC across all dosing cohorts of approximately 65%, including an 85% pathological



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response (6 of 7 patients) in the highest-dose cohort.

Phio has indicated that FDA engagement regarding next-stage clinical development is targeted for the second quarter of 2026 and has reported cash and cash equivalents projected to sustain operations into the first half of 2027.

About Phio Pharmaceuticals Corp.

Phio Pharmaceuticals Corp. (NASDAQ: PHIO) is a clinical-stage siRNA biopharmaceutical company advancing its INTASYL® gene silencing technology in immuno-oncology. Phio's INTASYL compounds are designed to enhance the body's immune cells to more effectively kill cancer cells. Notably, INTASYL is a self-delivering RNAi technology focused on immuno-oncology therapeutics without the need for formulation enhancements or manipulations to reach its target.

Phio's lead clinical program is an INTASYL compound, PH-762, that silences the PD-1 gene implicated in various forms of skin cancer. The Phase 1b trial (NCT# 06014086) evaluated PH-762 for the treatment of cutaneous squamous cell carcinoma, melanoma and Merkel cell carcinoma. PH-762 is a potential non-surgical treatment for skin cancers.

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. Examples of forward-looking statements contained in this press release include, among others, the possibility that our INTASYL® siRNA gene silencing technology will make the body's immune cells more effective in killing cancer cells, expectations that the U.S. manufacturer we have engaged with to manufacture our lead compound, PH-762, will produce the intended results, our projection that our current cash and cash equivalents will sustain operations into the first half of 2027, timing with respect to FDA engagement, and statements regarding our commercial and clinical strategy, development plans and timelines and other



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future events.

These statements are based only on our current beliefs, expectations and assumptions and 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 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.

Contact:

Phio Pharmaceuticals Corp.
Jennifer Phillips: jphillips@phiopharma.com
Corporate Affairs

Media:

David Shapiro
B2i Digital, Inc.
+1 212-579-4844
david@b2idigital.com
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