Phio Announces PH-762 Milestone with FDA Submission Supporting Clinical Development in Cutaneous Squamous Cell Carcinoma

Company Proposes Planned Phase 2b Neoadjuvant Study Following Successful Completion of Phase 1b Trial

KING OF PRUSSIA, PA, UNITED STATES, September 14, 2026 / EINPresswire.com/ -- 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, following the formal completion of the Phase 1b clinical study, it has submitted a meeting request and comprehensive briefing package to the U.S. Food and Drug Administration (FDA).



Phio Pharmaceuticals submitted a comprehensive briefing package to the FDA following completion of its Phase 1b PH-762 study, supporting the program's next stage of clinical development.

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The submission describes the nonclinical development program and integrated clinical pharmacology data for PH-762 and provides details of the completed Phase 1b study as well as the next planned Phase 2b neoadjuvant clinical study in cutaneous squamous cell carcinoma. The briefing package includes the scientific rationale, study design, and pharmacokinetic strategy intended to support the next stage of clinical development.

"Delivering this comprehensive briefing package to the FDA is a key achievement for the PH-762

program and an important step toward unlocking its clinical potential in cutaneous squamous cell carcinoma," said Robert J. Bitterman, President and CEO of Phio Pharmaceuticals. "We are encouraged by the Phase 1b findings and look forward to working with the FDA as we pursue the next phase of development."

Phio is currently preparing to manufacture clinical supplies for the next planned study, which are expected to be available in the first quarter of 2027. In addition, the dosing phase of the company's nonclinical toxicology study has been completed. Final activities supporting the next phase of clinical development are expected to be completed during the first quarter of 2027.



Phio advances PH-762 toward a planned Phase 2b neoadjuvant study in cutaneous squamous cell carcinoma following completion of its Phase 1b clinical study.

About Phio Pharmaceuticals Corporation

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>
> *Robert J. Bitterman, President & CEO of Phio Pharmaceuticals Corp.*

Phio Pharmaceuticals Corp. (NASDAQ: PHIO) is a clinical-stage biopharmaceutical company advancing its proprietary INTASYL® siRNA gene silencing technology to eliminate cancer. Phio's INTASYL compounds are designed to enhance the body's immune cells to more effectively kill cancer cells. Phio's lead clinical development 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, the potential for PH-762 to present a viable non-surgical alternative for skin cancer, our plans and expectations regarding FDA submissions and related interactions, including our intention to meet with the FDA to discuss potential next steps in the clinical trial design and development of PH-762, our belief that submission of our comprehensive briefing package to the FDA will support the next stage of clinical development of PH-762 and is an important step toward unlocking the PH-762 clinical potential in cutaneous squamous cell carcinoma, our belief that we will work with the FDA as we pursue the next phase of development of PH-762, our belief that activities supporting the next phase of clinical development of pH-762 are expected to be completed during the first quarter of 2027, and statements regarding our clinical strategy, development plans and timelines and other 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 of future FDA interactions on the development of our product candidates; our ability to work with the FDA; the development of our product candidates, results from our nonclinical, 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 risks identified in our most recent 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 U.S. Securities and Exchange Commission. 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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