November 4, 2025
Announcement no. 21

Progress Update on BioPorto's Adult Clinical Study

Copenhagen, Denmark, November 4, 2025, (GLOBE NEWSWIRE) – BioPorto A/S ("BioPorto" or the "Company") (CPH:BIOPOR), today announced an update on its ongoing adult clinical study in the US.

At the end of October 2025, BioPorto successfully completed patient enrollment in its clinical cut-off study. The Company is in the process of collecting the study data, and this process is taking more time than initially anticipated. To ensure the most effective design of the validation study, the Company has decided to submit a pre-submission meeting request to the US Food and Drug Administration (FDA) once the dataset has been analyzed, now expectedly in Q1 2026.

The clinical validation study is scheduled to begin following feedback from FDA, allowing BioPorto to proceed with a protocol aligned with FDA feedback. Accordingly, the FDA regulatory submission is postponed from the end of 2026 and into H1 2027. However, the Company continues to aim at a regulatory clearance in 2027 and thereafter initiating commercialization focused on the adult population in the US.

Carsten Buhl, BioPorto's Group Chief Executive Officer (CEO) commented: *"As we successfully completed patient enrollment and now are focusing on thorough data analysis, our commitment is to ensure the highest quality and most effective design for the validation study. While this means our FDA submission will shift into the first half of 2027, this approach derisks our design of the validation study."*

About BioPorto's Adult Clinical Study

BioPorto's clinical program evaluating an investigational in vitro diagnostic (IVD) urine NGAL assay is designed to aid in identifying adult patients at risk of developing moderate-to-severe acute kidney injury. The program includes a cut-off study to set the decision threshold and a separate clinical validation study, together supporting the FDA regulatory submission in 2027.

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About BioPorto

BioPorto is an in vitro diagnostics company focused on saving patients' lives and improving their quality of life with actionable kidney biomarkers – tools designed to help clinicians make changes in patient management. The Company leverages its expertise in assay development to create a pipeline of novel and compelling products that focus on conditions where there is significant unmet medical need, and where the

Company's tests can help improve clinical and economic outcomes for patients, providers, and the healthcare ecosystem.

The Company's flagship products are based on the NGAL biomarker and designed to aid in risk assessment and management of Acute Kidney Injury (AKI), a common clinical syndrome that can have severe consequences, including significant morbidity and mortality, if not identified and treated early. With the aid of NGAL levels, physicians can identify patients at risk of AKI more rapidly than is possible with current standard of care measurements, enabling earlier intervention and more tailored patient management strategies. The Company markets NGAL tests under applicable registrations including CE mark in several countries worldwide and FDA cleared ProNephro AKI™ (NGAL) in the US.

BioPorto has facilities in Copenhagen, Denmark and Boston, MA, USA. The shares of BioPorto A/S are listed on the Nasdaq Copenhagen stock exchange. For more information visit www.bioporto.com.

Forward looking statement disclaimer

Certain statements in this news release are not historical facts and may be forward-looking statements. Forward-looking statements include statements regarding the intent, belief or current expectations with respect to the Company's expectations, intentions and projections regarding its future performance including the Company's Guidance for 2025; currency exchange rate fluctuations; anticipated events or trends and other matters that are not historical facts, including with respect to implementation of manufacturing and quality systems, commercialization of NGAL tests, and the development of future products and new indications; concerns that may arise from additional data, analysis or results obtained during clinical trials; and, the Company's ability to successfully market both new and existing products. These forward-looking statements, which may use words such as "aim", "anticipate", "believe", "intend", "estimate", "expect" and words of similar meaning, include all matters that are not historical facts. These forward-looking statements involve risks, and uncertainties that could cause the actual results of operations, financial condition, liquidity, dividend policy and the development of the industry in which the Company's business operates to differ materially from the impression created by the forward-looking statements. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and other factors that could cause actual results to differ materially from those expressed or implied by such forward-looking statements. Given these risks and uncertainties, prospective investors are cautioned not to place undue reliance on forward-looking statements. Forward-looking statements speak only as of the date of such statements and, except as required by applicable law, the Company undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise. Factors that may impact BioPorto's success are more fully disclosed in BioPorto's periodic financial filings, including its Annual Report for 2024, particularly under the heading "Risk Factors".