March 18, 2026
Announcement no. 03

BioPorto Successfully Completes Preliminary Analysis of U.S. Adult NGAL Cutoff Study; Pre-Submission expected by End of Q1 2026

COPENHAGEN, DENMARK, March 18, 2026 – BioPorto A/S ("BioPorto" or "Company") (CPH: BIOPOR) today announced positive clinical readout update of the preliminary analysis of its U.S. adult NGAL Cutoff Study, designed to evaluate the clinical performance of NGAL in assessing risk of acute kidney injury (AKI). The Company intends to submit its FDA Pre-submission package by the end of March 2026, to ensure robustness in its subsequent Validation Study.

Patient enrollment was completed in October 2025, and database lock was finalized in March 2026. The preliminary analysis of the adult study has shown positive results supporting the study's primary endpoint, consistent with the findings from the Company's cutoff and validation study conducted in the pediatric segment, which subsequently led to FDA clearance at the end of 2023 for the pediatric indication. This is providing a strong foundation for BioPorto's regulatory strategy going forward.

BioPorto's Senior Medical Director, Dr. Prasad Devarajan, commented, "We are encouraged with the results from our interim analysis for the clinical performance of the BioPorto assay. The analysis reinforces our confidence that, upon completion of the study, the results provide strong support for the value of NGAL as a biomarker for identifying the risk of AKI in critically ill adults."

The planned Pre-submission will seek FDA's feedback on the regulatory pathway as well as the design of analytical and clinical study protocols for the Validation Study. Subsequently, the Validation Study will be initiated.

CEO Carsten Buhl stated: "This analysis is a major milestone for BioPorto. Support for our primary endpoint gives us the confidence to proceed with an FDA Pre-submission by the end of Q1. The Pre-Submission step is essential to ensure that we design and initiate the optimal Validation Study once we receive FDA feedback."

This announcement does not alter BioPorto's financial guidance as recently published on 5 February 2026.

To receive BioPorto's Company Announcements, Press Releases, Newsletters and other business relevant information, please sign up on https://bioporto.com/investor-contact/.

Investor Relations contacts

Niels Høy Nielsen, BioPorto A/S, investor@bioporto.com, C: +45 45290000

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 2026; 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".

About BioPorto

BioPorto is an in vitro diagnostics company focused on saving lives and improving the quality of life with actionable biomarkers – tools designed to help clinicians make changes in patient management. The Company uses its expertise in antibodies and assay development, as well as its platform for 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 the risk assessment and diagnosis of Acute Kidney Injury, 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 potentially 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.

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.