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Announcement no. 20

First Patient In - BioPorto Initiates Patient Enrollment for US Study of ProNephro AKI (NGAL)[™] for Adult Use at Massachusetts General Hospital

COPENHAGEN, Denmark and BOSTON, MA, USA, October 29, 2024, (GLOBE NEWSWIRE) - BioPorto A/S (BioPorto or Company) (CPH:BIOPOR), an in vitro diagnostics company focused on empowering the early detection of Acute Kidney Injury (AKI) today announced the enrollment of the first patient in its US clinical study for ProNephro AKI (NGAL)[™] with the goal of determining a cut-off point for risk stratification of moderate to severe of AKI in adult patients.

BioPorto's ProNephro AKI (NGAL), currently cleared by the US Food and Drug Administration (FDA) for those 3 months through 21 years of age, has been widely recognized for its groundbreaking potential in refining AKI diagnosis.

NGAL is a direct real-time marker of kidney cell damage and can potentially detect AKI days earlier than previously possible. Early detection of AKI may enable prompt intervention to save lives. BioPorto's proprietary assay is a kidney injury marker versus the traditionally used serum creatinine (SCr) functional test.

The cut-off study is the first of two studies which will form a substantial part of the submission for US clearance of ProNephro AKI (NGAL) in adult patients.

Peter Mørch Eriksen, Group CEO of BioPorto, commented: "With strong interest from participating clinics and hospitals, forceful dedication from our team and leveraging our experience from the pediatric clearance process successfully concluded in 2023, we have progressed from a draft protocol to now enrolling the first patients at Massachusetts General Hospital, MA (US) in a very short time. I am very encouraged by the momentum we have kept, which has allowed us to speed up and commence enrollment ahead of our original plans. Accelerating the clinical process and obtaining FDA clearance for the adult test will be a very important milestone in providing clinicians this new important tool for assessing risk for clinically significant AKI, and opening up a global market valued at more than USD 3 billion annually."

The cut-off study seeks to enroll patients at up to 12 US sites in 2024 and 2025. After having established the cut-off, BioPorto expects to commence enrollment for the second study, the validation study, enabling the Company to submit its FDA application for adult usage of ProNephro AKI (NGAL) by 2026.

The content of this announcement does not change BioPorto guidance for 2024, as most recently described in its Interim Report for the second quarter of 2024.

This announcement has been prepared in English and Danish. In case of discrepancy, the English version shall prevail.

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

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About Acute Kidney Injury

Acute kidney injury is a sudden episode of kidney failure or kidney damage that happens within a few hours or a few days. AKI causes a build-up of waste products in blood and makes it difficult for kidneys to maintain the proper balance of bodily fluids. AKI can also affect other organs such as the brain, heart, and lungs and is common in patients who are in hospital intensive care units. For more information about AKI please visit: <https://bioporto.com/aki/>.

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.

Forward-looking Statements

This announcement may contain certain forward-looking statements. Words such as "initiate", "may", "focus", "design", "guide", "plan", "estimate", "expand", "target", "potentially", "will", "should" and similar expressions identify such forward-looking statements, and such forward looking statements include statements with respect to commercialization activities in the U.S. and elsewhere, our collaboration with strategic partners, our ability to obtain regulatory approval to expand indications to analyzers other than the cobas c 501 or to other age groups and/or clinical indications, the buildout of our commercialization team and our financial guidance. Forward-looking statements involve risks, uncertainties and other factors, which may cause actual results, performance and achievements to differ materially from those contained in the forward-looking statements. These include numerous assumptions, risks and uncertainties, many of which are beyond BioPorto's control. These assumptions, risks and uncertainties are

described from time to time in BioPorto's public announcements, its Interim Reports, and in its 2023 Annual Report under Risk Factors. BioPorto undertakes no obligation to publicly update or revise forward-looking statements to reflect subsequent events or circumstances after the date of this presentation, except as required by applicable law.