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BioPorto Receives FDA 510(k) Clearance for NGAL Test in the United States
First Test to Aid in Assessing AKI Risk for Patients Aged 3 Months Through 21 Years

COPENHAGEN, DENMARK and BOSTON, MA, December 7, 2023, (GLOBE NEWSWIRE) – BioPorto A/S (BioPorto or the Company) (CPH:BIOPOR), today announced receipt of a US Food and Drug Administration (FDA) 510(k) clearance for BioPorto's NGAL test, to be marketed as ProNephro AKI™ (NGAL).

ProNephro AKI (NGAL) is the first Acute Kidney Injury (AKI) biomarker test cleared for pediatric use (aged 3 months through 21 years) in the US. ProNephro AKI (NGAL) is designed to help doctors identify patients at risk of developing or having persistent, moderate-to-severe AKI within 48-72 hours in the intensive care unit (ICU) setting. Unlike serum creatinine, a muscle by-product that is the current standard of care but slow to rise in AKI, NGAL is a direct real time marker of kidney cell damage and can potentially detect AKI days earlier than serum creatinine. Early detection of AKI may enable prompt intervention to save lives.

"With the FDA's 510(k) clearance for ProNephro AKI (NGAL) on the Roche cobas® c 501 analyzer, we are excited to launch BioPorto's US commercialization efforts," said Tony Pare, BioPorto's Chief Executive Officer. "This milestone will provide the first STAT laboratory test to aid in the assessment of AKI in pediatric patients. Pediatric intensive care is a beachhead where we aim to demonstrate the life- and cost-saving value of ProNephro AKI (NGAL). Pediatric is the first segment of the $1.2 billion US and $3 billion worldwide markets[1] for AKI detection."

Mr. Pare continued, "We accomplished what we set out to do, and I am very proud of the BioPorto team that achieved this key step for the Company, hospital patients, and our shareholders."

Until now, the risk for developing or having persistent AKI has been difficult to assess early because current standard-of-care methods, such as sCr, rise slowly in AKI. As such, ProNephro AKI (NGAL) was developed to help save kidneys and lives through faster and more timely intervention.

"Now, clinicians will have a new and biologically credible AKI test at their disposal," said BioPorto's Senior Medical Director and co-discoverer of NGAL, Dr. Prasad Devarajan, Professor of Pediatrics & Developmental Biology, Director of Nephrology and Hypertension, and CEO of the Dialysis Unit at Cincinnati Children's Hospital Medical Center* (Ohio, US). "NGAL is well studied and enables a more personalized approach to the early management of AKI, as demonstrated by our extensive work in the ICU setting."

**Cincinnati Children's Hospital does not endorse any commercial products or companies*

[1] Management estimates. Includes all potential applications (including all brands of clinical chemistry analyzers and outpatient monitoring) in pediatric and adult patient populations. S2N. Data on file.

Commercialization and Next Steps

BioPorto expects that US sales through its distribution agreement with Roche Diagnostics GmbH (Roche) will begin in the second half of 2024. In advance of that, BioPorto will follow Roche's processes to add approved assays to its portfolio. BioPorto also intends to:

- expand the clinical chemistry diagnostic instruments on which ProNephro AKI (NGAL) is cleared beyond the Roche cobas c 501 to additional Roche instruments;
- expand ProNephro AKI (NGAL) clearance to other manufacturers' instruments; and,
- run clinical studies intended to expand NGAL use for adult indications.

BioPorto will start scaling the organization, including its commercial and R&D teams, to accomplish product launch and indication expansion objectives. BioPorto's Board is assessing the capital requirements associated with all the above activities.

The content of this announcement does not alter BioPorto's financial guidance for 2023 as most recently presented in the November 1, 2023 Interim Report.

If you wish to receive BioPorto's Company Announcements, Press Releases, Newsletters and other business relevant information, please sign up on BioPorto's webpage.

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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 contains 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, the performance and efficacy of ProNephro AKI (NGAL), the worldwide total addressable market for ProNephro AKI (NGAL), our collaboration with Roche Diagnostics GmbH (Roche) and Roche's market position, 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, our ability to raise additional capital on terms acceptable to us, the buildout of our commercialization team, our financial guidance and the statements included herein under the heading "Commercialization and Next Steps". 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 2022 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.