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Roche Diagnostics and BioPorto expand collaboration

COPENHAGEN, DENMARK and BOSTON, MA, 20 February, 2024, (GLOBE NEWSWIRE) – BioPorto A/S (BioPorto or the Company) (CPH:BIOPOR), has today announced an expansion of its strategic collaboration with Roche Diagnostics.

As announced on December 7, 2023, BioPorto received FDA clearance in the US for its NGAL test to be marketed as ProNephro AKI™ (NGAL) on Roche's cobas® c 501.

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.

In continuation of the FDA approval, BioPorto and Roche Diagnostics today have expanded the existing global distribution agreement for the cobas c 501 and c 502 analyzers to also include the cobas c 503 analyzer.

Peter Mørch Eriksen, CEO of BioPorto, comments "I am very pleased to expand the strategic collaboration with Roche Diagnostics, which is a dominant player in the diagnostic space. This is an important step in the execution of our instrument expansion strategy and will ensure a broader distribution of our NGAL test and address a critical need in relation to risk assessment and early diagnosis of acute kidney injury. We will now work together with Roche towards expanding our test to the c 503 analyzer and prepare for commercialization."

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.

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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 (from American Kidney Association: https://www.kidney.org/atoz/content/AcuteKidneyInjury). 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.