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BioPorto Submits Application for Marketing Authorization of NGAL Test to the US Food and Drug Administration

COPENHAGEN, DENMARK and BOSTON, MA, USA, November 10, 2022, (GLOBE NEWSWIRE) -- BioPorto A/S (BioPorto or Company) (CPH:BIOPOR) has announced the submission of a De Novo application to the US Food and Drug Administration (FDA) of a neutrophil gelatinase-associated lipocalin (NGAL) test to aid in identifying pediatric patients (≥3 months to <22 years) at risk of moderate to severe AKI. The submission is supported in part by results from the recently completed GUIDANCE trial, which exceeded the Company's prespecified targets for test performance.

The NGAL test received FDA Breakthrough Device Designation and is therefore expected to receive expedited review. If granted by the FDA, the NGAL test would be the first authorized pediatric AKI biomarker test commercially available in the US. The De Novo pathway creates a new classification for medical devices that do not have a predicate device for comparison.

"This FDA submission is the next major milestone in the strategy BioPorto set in early 2022, focused on making our flagship product available to US-based physicians and lab directors who work with critically ill patients," said Tony Pare, BioPorto's Chief Executive Officer. "The US market is anticipating this important and potentially lifesaving test that addresses a highly underserved patient population. I am proud of our team and their commitment to its launch."

"Physicians caring for the most critically ill patients routinely rely on tools to assess risk for worsening illness and outcomes," explained Dr. Stuart Goldstein, MD, FAAP, FNKF, FASN and Principal Investigator for the GUIDANCE clinical study establishing the clinical benefit of the NGAL test. "Previous to the NGAL test, we lacked such a tool to measure AKI, which afflicts as many as one quarter of hospitalized patients, increasing their risk of serious morbidity and mortality. The data from GUIDANCE clearly suggests that the NGAL test provides highly specific, near real-time detection of AKI that can be integrated with clinical acumen to attend to those patients truly at risk for the devastating consequences of AKI."

"Assessing the risk of AKI in critically ill patients currently relies on changes in serum creatinine and urine output, but both are delayed, non-specific, and impacted by other factors such as nutritional status and muscle mass," said Dr. Christopher Bird, BioPorto's Chief Medical Officer. "With data from 16 hospitals across the US, GUIDANCE corroborated results from many peer-reviewed publications that show NGAL rises within hours of kidney injury, as much as 2-3 days sooner than serum creatinine. With earlier detection of patients at risk of AKI, clinicians can act more quickly to manage fluid levels, medications, and nephrotoxic agents, and potentially prevent permanent kidney damage."

While awaiting the FDA's review of the submission, BioPorto will continue executing its commercialization strategy, including hiring personnel and continuing to prepare manufacturing and quality systems, while working to make the test available for the adult (age 22 and over) populations.

This announcement does not alter BioPorto's financial guidance for 2022 as most recently presented in the Interim Report for Third Quarter 2022.

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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 product, The NGAL Test™, is designed to aid in the risk assessment 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 The NGAL Test, 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 NGAL Test is CE marked and registered 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 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, anticipated events or trends and other matters that are not historical facts, including with respect to potential FDA marketing authorizations, 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 with the Danish Financial Supervisory Authority, particularly under the heading "Risk Factors".