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BioPorto Achieves Targeted Enrollment in Clinical Study Supporting FDA De Novo Submission for The NGAL Test in the U.S.

COPENHAGEN, DENMARK and BOSTON, MA, USA, June 28, 2022, (GLOBE NEWSWIRE) -- BioPorto A/S (BioPorto) (CPH:BIOPOR) today announced its achievement of targeted subject enrollment for the third part of a 3-part clinical study to support a U.S. Food and Drug Administration (FDA) De Novo submission for use of The NGAL Test in identifying patients under the age of 22 at risk for Acute Kidney Injury (AKI).

"We are very pleased to have reached the study's planned enrollment of 600 patients by the end of Q2, as previously guided," said Dr. Christopher Bird, BioPorto's Chief Medical Officer. "We are now reviewing the clinical data to confirm that no additional data is required, after which we will perform an in-depth data analysis, complete the other required technical and analytical material, and submit the application to the FDA for De Novo approval."

Based on the quality of the clinical data and other material to support the desired claims, BioPorto anticipates submission of its De Novo application to the FDA by the fourth quarter of 2022.

The NGAL Test has been granted Breakthrough Device designation by the FDA for expedited review. Breakthrough Device designation is granted for devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions, and where neither approved nor cleared alternatives exist.

"Achieving targeted enrollment is a major milestone in BioPorto's strategy, which is focused on obtaining FDA clearance and initial U.S. commercialization of our flagship product, The NGAL Test," said Tony Pare, BioPorto's Chief Executive Officer. "I am very proud of how our team and clinical partners sustained momentum during the pandemic and executed according to the plan we established. We are now directing the bulk of our energy into finalizing and submitting the application to the FDA and preparing to make the test available to clinicians so they may better tailor care of critical ill patients."

This announcement does not alter BioPorto's financial guidance for 2022 as most recently presented in the Interim Report for First 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 is The NGAL Test, which has been 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 a number of 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 the potential FDA clearance, commercialization of The NGAL Test, and the development of future products and new indications. 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".