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News release

BioPorto Provides Update on NGAL Test Regulatory Pathway

COPENHAGEN, DENMARK and BOSTON, MA, September 11, 2023, (GLOBE NEWSWIRE) -- BioPorto A/S ("BioPorto" or "the Company") (CPH:BIOPOR), today announced that based on direction from the US Food and Drug Administration (FDA), it decided to change the regulatory pathway for the Company's NGAL test from a De Novo to a 510(k).

This is not expected to impact the FDA's ongoing review process.

"We are pleased that the FDA is permitting BioPorto to change to the 510(k) pathway by applying principles from the FDA's *Least Burdensome Provisions* guidance, which require 'the most efficient manner'[1] to expeditiously get this important test with breakthrough device status to the US market. We appreciate the FDA's ongoing collaboration, which includes maintaining the same review team and continued interactive dialog," said Tony Pare, BioPorto's Chief Executive Officer. "We remain 100% focused on the approval process."

The FDA's DeNovo pathway leads to approval of a new regulatory classification and marketing authorization of the associated product, whereas the 510(k) pathway leads to marketing authorization of a product using an existing regulatory classification.

If the FDA grants marketing authorization, BioPorto's NGAL test would be the first authorized pediatric Acute Kidney Injury (AKI) biomarker test commercially available in the US.

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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.

[1] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles

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 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 news release contains certain forward-looking statements. Words such as "believe", "expect", "may", "plan", "strategy", "estimate", "target" and similar expressions identify such forward-looking statements, and such forward looking statements include statements with respect to the U.S. regulatory approval process of BioPorto's NGAL test, the FDA's activities related to its regulatory review, the nature and extent of the Company's dialog with the FDA, future commercialization opportunities for NGAL tests in the US and around the world, and other matters. 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.