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Announcement no. 19

BioPorto submits answers to the FDA regarding The NGAL Test™ for risk assessment for AKI in pediatric patients

BioPorto A/S (BioPorto) announces today that, following substantive dialog with the U.S. Food and Drug Administration (FDA) and detailed data analysis, it has decided to supplement, rather than withdraw, its application for pediatric use of The NGAL Test™ for risk assessment of acute kidney injury (AKI).

In May 2019, BioPorto submitted its application to the FDA for marketing clearance of The NGAL Test for risk assessment of pediatric AKI. The FDA responded in July with an Additional Information (AI) letter outlining questions that needed to be resolved in order to continue review of BioPorto's 510(k). Initially, the Company assessed that the questions in the AI would necessitate withdrawing and resubmitting its application.

However, in recent months, as BioPorto conducted an in-depth data review, obtained expert input, and had a series of productive interactions with the FDA, the Company constructed a response to the AI letter. The completed response was submitted today, which allows the 510(k)-clearance process to continue.

Today's decision to continue with the original 510(k) application does not alter BioPorto's financial guidance for 2019, which was recently presented in the Interim Report for the Second Quarter of 2019.

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About BioPorto
BioPorto is an in vitro diagnostics company that provides tests and antibodies to clinicians and researchers around the world. We use our antibody and assay expertise to transform novel research tools into clinically actionable biomarkers that can make a difference in patients' lives. BioPorto is headquartered in Hellerup, Denmark and is listed on the NASDAQ Copenhagen stock exchange [CPH:BIOPOR].