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Announcement no. 14

BioPorto to redraw U.S. application for regulatory clearance of The NGAL Test™ for risk assessment for AKI in patients under the age of 22 with the intend to resubmit in Q4 2019

BioPorto A/S ("BioPorto") announces today that the company has received an Additional Information ("AI") request letter from the U.S. Food and Drug Administration ("FDA") regarding the application for regulatory clearance of the NGAL Test for risk assessment of acute kidney injury ("AKI") in critical ill patients under the age of 22.

The AI request primarily concerns the clinical study data and collection of retrospective samples, which has been collected in close collaboration with leading kidney specialists at Cincinnati Children's Hospital in U.S. BioPorto has reviewed FDA's AI request and concluded, that the existing clinical studies and data do not constitute sufficient basis to proceed with the current application. Therefore, the current application will be redrawn.

BioPorto will now engage in a dialogue with Cincinnati Children's Hospital and other leading U.S. children hospitals to collect additional retrospective clinical samples. BioPorto will resubmit a new package to FDA during Q4 2019 under the assumption that the clinical sample selection will start in August 2019.

BioPorto and leading kidney specialists in U.S. remain committed to NGAL as an important biomarker for AKI and other indications and will continue discussions with the FDA on potential paths going forward to obtain regulatory clearance of both The NGAL Test for risk assessment of AKI in patients under the age of 22 and the NGAL Test (plasma) for risk assessment of AKI in adults, which is expected to be submitted to FDA later in 2019.

As a consequence of the redraw, BioPorto suspends its financial guidance for 2019 until the publication of the interim report for first half of 2019, which will be published on August 15th 2019.

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About BioPorto

BioPorto is an in-vitro diagnostics company that provides healthcare professionals in clinical and research settings a range of diagnostic tests and antibodies. BioPorto has its headquarters in Hellerup, Denmark and is listed on the NASDAQ Copenhagen stock exchange.