July 2, 2019
Announcement no. 12

Adjustment of timeline for FDA decision regarding application for pediatric clinical use of The NGAL Test™

BioPorto A/S ("BioPorto") announces today that the timeline for the company's application for regulatory clearance of The NGAL Test™ in the U.S. for risk assessment of acute kidney injury ("AKI") in children under the age of 22 with the U.S. Food and Drug Administration ("FDA") has been adjusted.

BioPorto has since the submission of the application in May 2019 been engaged in an active and positive dialogue with the FDA regarding the application process under Breakthrough Designation. As part of this dialogue, FDA has announced that it will forward questions to the application on July 19, 2019. Consequently, a decision regarding the application could be expected by end-August 2019/early-September 2019.

The content of this announcement does not alter BioPorto's financial guidance for 2019 as most recently expressed in the Interim Report for the First Quarter 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.