October 3, 2018
Announcement no. 17

BioPorto receives communication from FDA regarding The NGAL Test™

BioPorto A/S ("BioPorto") announces today that the company has received communication from the U.S. Food and Drug Administration ("FDA") regarding the application for regulatory clearance of The NGAL Test™ for risk use with acute kidney injury in the U.S.

The communication states that additional data will be required to support the AKI rule-out claim in order to continue the application process. BioPorto will now enter into a dialogue with FDA to further clarify these issues. Based on the foregoing, Management's expectation as to the timing of FDA's decision regarding clearance of The NGAL Test ™ is therefore postponed to mid-2019.

BioPorto will continue its evaluation of the matters addressed in the communication from the FDA and will announce any new material decision or news regarding the NGAL approval process.

The content of this announcement does not alter BioPorto's financial guidance for 2018 as most recently expressed in the interim report for the second quarter of 2018.

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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.