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Announcement no. 7

BioPorto Submits Pediatric Application to FDA for The NGAL Test™ Under Breakthrough Designation

First test focused on risk assessment of Acute Kidney Injury in pediatric patients

BioPorto A/S ("BioPorto") announces today that the company has submitted an application to the U.S. Food and Drug Administration ("FDA") 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 21.

Strong performance of The NGAL Test using international, retrospective sample set
BioPorto's application is based on a retrospective set of samples of urinary NGAL in children originally tested with the BioPorto NGAL ELISA test in 2014. The samples were originally obtained as part of the Assessment of Worldwide Acute Kidney Injury, Renal Angina, and Epidemiology (AWARE) study by Ahmad Kaddourah, M.D., Rajit K. Basu, M.D., Sean M. Bagshaw, M.D., and Stuart L. Goldstein, M.D. It involved 4,683 patients from 32 pediatric ICUs across Asia, Australia, Europe and North America. Of the patients evaluated, 1,261 developed AKI and 543 patients developed severe AKI.

In this study, BioPorto has re-tested a subset of the original samples using The NGAL Test, its new automated assay. These results were compared to the original adjudicated AKI status to demonstrate The NGAL Test's ability to predict the risk of patients developing moderate to severe AKI. The NGAL Test results were also compared to the original ELISA result, demonstrating the bridging performance of the two test methodologies. In the newly submitted data, The NGAL Test had a sensitivity of 65.0% and specificity of 81.8% with a negative predictive value of 95.4%. BioPorto believes these are strong results that support the potential of The NGAL Test to be a clinically valuable tool to help clinicians better assess AKI risk in critically ill children.

FDA grants Breakthrough Designation for The NGAL Test: expected review period of 45 days
The NGAL Test for pediatric risk assessment has been granted designation as a Breakthrough Device by FDA, identifying that it may "provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions". Receiving this designation means that BioPorto's application will receive priority review, reducing the expected FDA review period from 90 days to 45 days. As a result, a decision regarding the application could be received before the end of July 2019, assuming a standard FDA review timeline for Breakthrough Devices.

The submission of this FDA application 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.