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Announcement no. 16

BioPorto initiates pivotal clinical study with The NGAL Test™ for children

BioPorto A/S ("BioPorto") announces today that the company has initiated a pivotal retrospective clinical pediatric NGAL study regarding risk use with acute kidney injury ("AKI"). The study will form the basis for an additional application for U.S. Food and Drug Administration ("FDA") regulatory clearance of The NGAL Test™ in the U.S. for clinical use (IVD) in children under the age of 18. BioPorto expects to submit an application to the FDA in the first half of 2019.

Significant interest and potential for The NGAL Test™ in pediatrics

Clinical attention to pediatric urine NGAL as a useful early biomarker for risk of developing AKI in critically ill children has increased considerably. With more than 300 dedicated pediatric hospitals in the U.S. and a significant interest in BioPorto's The NGAL Test™ from pediatric departments in general hospitals, there is an unmet need and huge potential for BioPorto's test to address.

"One in four critically ill pediatric patients in the intensive care unit (ICU) suffers from AKI. These children will often have prolonged time on ventilators, higher rates of infection, longer stays at the hospital and increased rates of death – potentially consequences of reliance on delayed and imprecise current diagnostic standards. The limitation in detection may be limiting doctors' abilities to get ahead of injury as the status quo only detects AKI at a late stage. NGAL is a real-time tool, potentially allowing us to be proactive instead of reactive, which is crucial in the intensive care unit. Tests like the NGAL Test™ should ultimately improve the care of the kidney dysfunction in patients," who are critically ill," says Rajit Basu, MD, Director of Research, Critical Care Medicine and associate professor of Pediatrics, Children's Healthcare of Atlanta.

"By initiating this study and expectedly receiving FDA clearance of the test for pediatric use, we will be able to accelerate the speed with which physicians and clinics can implement the test and achieve early indication of AKI in children. We are highly optimistic, eager and motivated by these prospects, which are fully aligned with our strategy of deploying the NGAL technology and The NGAL Test™ widely in healthcare to ensure better care of critically ill patients and to improve overall healthcare economics," says Peter Mørch Eriksen, CEO of BioPorto.

Retrospective study based on urinary NGAL

BioPorto's clinical study will be performed using a retrospective set of samples of urinary NGAL in children originally tested with the BioPorto NGAL ELISA test in 2014. The samples will be re-tested with The NGAL Test™, and the results compared to the adjudicated AKI status from the original study. Predictive values of the test compared to AKI status will be analyzed and the original results will be compared to the re-tested results to demonstrate bridging performance of the two methodologies.

Expectations for 2018 unaffected

The initiation of the study does not affect the company's financial guidance for 2018 as latest expressed in the interim report for the second quarter of 2018.

In addition to the pediatric study and application, BioPorto has in July 2018 submitted an U.S. application for The NGAL Test™ for risk use with AKI in adults, which is pending FDA clearance.

For further information, please contact:

Peter Mørch Eriksen, CEO
Ole Larsen, CFO
Telephone +45 4529 0000, e-mail investor@bioporto.com

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.