November 18, 2019
Announcement no. 20

BioPorto to provide additional patient information in support of its US application for regulatory clearance of The NGAL Test™ for pediatric risk assessment of Acute Kidney Injury

BioPorto A/S (BioPorto) announces today that following recent dialog with the US Food and Drug Administration (FDA), it has decided to supplement its pediatric 510(k) application with additional data in order to fully respond to the most recent review shared by the Agency.

The valuable study from which BioPorto drew its original dataset was published in the premier clinical journal – *The New England Journal of Medicine*. These data demonstrated that the NGAL biomarker can be successfully deployed to assess risk of pediatric acute kidney injury (AKI) in the critical care setting. However, the FDA disagreed with the clinical community, expressing concern over risk of clinician bias in the data.

Although disappointed in the short-term setback, BioPorto remains committed to addressing the significant unmet medical need for better tools to help doctors evaluate and manage critically ill patients at risk of AKI. The Company will take the insights gained into FDA's thinking and approach and will use this knowledge to build a follow-on dataset designed to demonstrate NGAL's utility not only to clinicians, but also to FDA. The Company expects to submit a revised and supplemented application in Q2 2020, with the adult application to follow.

"Moving forward, BioPorto also has the opportunity to use our deeper understanding of FDA's requirements to improve and augment our ongoing adult studies and our planned future indications for NGAL," said Peter Mørch Eriksen, BioPorto's CEO. "While we differ in the degree to which we trust clinician judgment, BioPorto has benefitted from and appreciated the candid dialog with FDA and we are looking forward to continued collaboration in our joint goal to improve and protect patient health."

As a consequence, BioPorto's financial guidance will change from revenue of approximately DKK 32 million to approximately DKK 29 million and EBIT for 2019 will change from a loss of approximately DKK 65 million to a loss of approximately DKK 70 million.

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 tests and antibodies to clinicians and researchers around the world. We use our antibody and assay expertise to transform novel research tools into clinically actionable biomarkers that can make a difference in patients' lives. BioPorto is headquartered in Hellerup, Denmark and is listed on the NASDAQ Copenhagen stock exchange [CPH:BIOPOR].