October 10, 2016
Announcement no. 18

BioPorto files Pre-Sub application for The NGAL Test™ to the FDA

BioPorto A/S (BioPorto) has now submitted a pre-submission to obtain FDA feedback on the proposed clinical trial protocol and the application for regulatory approval of The NGAL Test for clinical use (IVD) in the USA. BioPorto has been in close dialogue with the FDA to discuss and fully understand the issues with the first application, which was denied earlier this year. BioPorto is confident that these issues are addressed in the new pre-submission.

Given the timeframe of a pre-submission with the FDA and allowing for any changes to the protocol, enrollment of patients is expected to commence in second quarter of 2017. BioPorto maintains the expectation that an approval can be obtained by mid-2018.

Elisabeth Erhardtsen, VP Clinical and Regulatory Affairs of BioPorto, states: "Our pre-submission today marks the official starting point of the revised application process with the FDA. I am confident that we are on the right track to ensure the desired outcome which is an approval in less than two years. NGAL is an important biomarker already in demand in clinical settings and it could significantly improve patient outcomes. This is why we are diligently working on our clinical trial protocol. "

BioPorto has allocated DKK 3 million to the FDA process in 2016. The expected cost of the clinical trial commencing in 2017 and the following steps towards an approval will be determined during the pre-submission process, as this could influence the scale and scope of the trial. The Company's financial outlook for 2016 is maintained.

For further information, please contact:
Peter M. Eriksen, CEO
Christina Thomsen, Investor Relations Manager
Telephone +45 4529 0000, e-mail investor@bioporto.com

The kidney biomarker NGAL
Every year about 13 million people are struck by acute kidney injury worldwide, of which about 4 million die. Nevertheless, there has been no real progress in methods of diagnosing kidney injury over the last half century. Existing methods, such as serum creatinine determination, only signal kidney failure 24-72 hours after the injury has taken place. In contrast, NGAL rises to diagnostic levels within a few hours of kidney injury and thus enables the physician to make vital clinical decisions before the damage progresses to potentially fatal renal shutdown.

About BioPorto
BioPorto Diagnostics A/S is an in-vitro diagnostics company that provides healthcare professionals in clinical and research settings a range of diagnostic tests and antibodies. Our pioneering product portfolio includes assays for underserved disease states such as NGAL for acute kidney injury. BioPorto has its headquarters in Copenhagen, Denmark and is listed on the Nasdaq Copenhagen stock exchange.