May 28, 2016
Announcement no. 13

The FDA rejects application for the registration og The NGAL Test™

The Food and Drug Administration (FDA) has informed BioPorto A/S (BioPorto) that the registration application for The NGAL Test™ has been rejected on the grounds that the submission does not provide adequate clinical and analytical data to support a reasonable assurance of approval of the device.

FDA's response means that BioPorto cannot begin commercialization of The NGAL Test™ for clinical use in the US as previously expected, whereas sales for research use continues.

Peter M. Eriksen, CEO of BioPorto, said: "We are obviously disappointed and very surprised by the FDA's rejection of our application for registration of The NGAL Test™. It is certainly not the outcome we expected, and obviously a major setback for BioPorto and our strategy. As previously announced, we believe that the data is good. It has now been found not to be sufficient when it comes to mild cases of acute kidney injury. We take note of the rejection and we will now enter into dialogue with the FDA and our advisors on how a any revised application process can be made. Such process will take time, and I do not expect it could be completed this year. In parallel, we will intensify our sales focus on our existing products and markets, where growth is already strong and the potential great. "

Adjustment of expectations
BioPortos revenue expectations for 2016 were based on the approval and launch of The NGAL Test™ in the US in the second quarter of 2016. As a result of the FDA's rejection of the application, expectations for 2016 are adjusted to revenues of around DKK 23-26 million (previously around DKK 27-30 million) and an operating loss (EBIT) of 16-18 million (previously a loss of around DKK 11-13 million).

For further information, please contact:
Peter Mørch Eriksen, CEO
Christina Thomsen, Investor Relations Manager
Telephone +45 4529 0034, e-mail investor@bioporto.com

The kidney biomarker NGAL
Every year about 13 million people are struck by acute kidney injury worldwide, of whom 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.