Match 6, 2018
Announcement no. 4

BioPorto finalizes enrolment of patients for The NGAL Test™ clinical study in the US and plans submission of FDA application in Q2 2018.

BioPorto has enrolled the last patient today in the clinical study that will generate data for BioPorto's FDA application for The NGAL Test™ in the US.

Patient enrolment had been slightly extended at the 17 leading medical institutions to secure additional patients with acute kidney injury (AKI) for the study. In addition, new activities were added to the study to address inclusion of the Roche instruments covered under the distribution agreement executed on February 9th, 2018. Having concluded the enrolment, BioPorto expects to submit its registration application for The NGAL Test™ to the FDA in the second quarter of 2018.

Assuming a normal and successful review and approval process, registration is likely to be obtained in the second half of 2018.

"Having finalized the enrolment, we pass yet another important milestone in the process for obtaining registration approval for The NGAL Test™ by the FDA. We are now full-speed ahead on analysing the data and finalizing the application which, subject to FDA approval, will enable us to initiate commercialization of a clinically approved test in the US, the world's largest market for diagnostics. Together with the distribution agreement with Siemens Healthcare in 2016 and the recently announced distribution agreement with Roche Diagnostics, this will be a major stepping stone in realizing the huge market potential for The NGAL Test™ going forward," says Peter Mørch Eriksen, CEO of BioPorto.

For further information, please contact:

Peter Mørch Eriksen, CEO
Gry Husby Larsen, General Counsel
Telephone +45 4529 0000, e-mail investor@bioporto.com

The kidney biomarker NGAL

Every year approximately 13 million people are struck by acute kidney injury worldwide, of whom about 4 million dies. Nevertheless, there has been no real progress in the 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. In addition to helping the patient, cost-benefit analyses show that implementing NGAL testing will contribute to reducing hospital costs in the management of kidney injury and its consequences.

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. We sell our products in more than 80 countries through diverse sales channels and partners. BioPorto has its headquarters in Copenhagen, Denmark and is listed on the NASDAQ Copenhagen stock exchange.