January 30, 2017
Announcement no. 1

BioPorto completes pre-submission discussions with the FDA regarding its protocol for the clinical evaluation of The NGAL Test ™.

BioPorto presented a new pre-submission document to the FDA in October 2016 incorporating a new protocol for a clinical trial that is intended to obtain data for submission for regulatory approval of The NGAL Test ™ for clinical use (IVD) in the United States.

Since then, BioPorto and its advisers have been in close dialogue with the FDA, and the content of the Pre-submission where examined by and discussed with authority representatives in December 2016. Based on the FDA's feedback, BioPorto has finalized the protocol that will form the basis of the company's submission in the United States. The next dialogue with the FDA is expected to occur after filing the application and BioPorto is hopeful for an approval in mid-2018.

Elisabeth Erhardtsen, VP Clinical and Regulatory Affairs in BioPorto, commented: "Our discussions with the FDA have been very constructive. We have finalized our protocol for the clinical trial, selected our clinical sites and are moving forward with our study to meet the expected timelines."

Peter Mørch Eriksen, CEO of BioPorto, commented: "Since May of last year when we received the disappointing news from the FDA regarding our application, we have strengthened our organization and cooperation with external advisors to ensure the most optimal starting point for our new application. I am therefore very pleased to note, that our efforts have resulted in a strong foundation for our new clinical trial. "

The budget for the clinical trial will appear in the company's annual report for 2016, as announced on 15 March 2017.

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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. 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.