10th April 2015
Announcement no. 09

Enrollment for the clinical trial of The NGAL Test™ in the US has been completed

BioPorto have ultimo March 2015 completed the enrollment of patients for the clinical trial, which secures the data which will be part of the US submission of The NGAL Test™. It is expected to submit to the US Food and Drug Administration, FDA during Summer 2015.

Peter Mørch Eriksen, CEO of BioPorto, states: "The enrollment from a total of 250 Intensive Care Unit (ICU) patients has followed our plan as laid out and we have experienced strong collaboration with Massachusetts General Hospital in Boston, Montefiore Medical Center in New York and Methodist Hospital in Houston. The analysis results of the patient samples from the clinical study forms the data, which will be included in the submission to the FDA, and we expect a US FDA approval by the end of 2015. Following this we will commence the roll-out of the NGAL Test™ on the largest in vitro diagnostic market in the world, which will be a major strategic milestone for BioPorto."

The completion of the enrollment and the wording of this message will not lead to any change of the expectations to BioPortos turnover and result in 2015 - latest expressed in The Annual Report 2014.

Further details from:
Peter Mørch Eriksen, CEO
Phone 45 29 00 00, 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. 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 OMX Copenhagen stock exchange.