June 27, 2018
Announcement no. 12

BioPorto has finalized clinical studies enabling submission of the FDA application for The NGAL Test™ in July 2018

BioPorto A/S ("BioPorto") has successfully completed clinical studies for The NGAL Test™ in collaboration with leading US hospitals. The data collected is being statistically processed and analyzed. This will be used for finalizing the application to the US Food and Drug Administration for regulatory approval of The NGAL Test™ for acute kidney injury in the United States of America.

BioPorto filed a pre-submission in late-2016, followed by protocol development in early 2017 and patient recruitment in Q2 2017. Since then more than 500 patient cases have been collected at 17 hospital sites in the US, including Yale, Cleveland Clinic, Houston Methodist Hospital and Massachusetts General Hospital.

The analytical studies and patient testing have been fully completed, and BioPorto's external CRO partner is in the process of finalizing the statistical data analysis. The results will be available shortly, and BioPorto expects to submit the application for registration of The NGAL Test™ in July 2018.

The content of this announcement does not affect BioPorto's financial guidance for 2018 as most recently expressed in the interim report for the first quarter 2018.

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 about 13 million people are struck by acute kidney injury worldwide, of whom about 4 million dies. 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 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.