**July 4, 2016**
**Announcement no. 14**

## BioPorto decides to reapply for FDA approval of The NGAL Test™

BioPorto A/S (BioPorto) has decided to reapply for approval of the Company's kidney injury test, The NGAL Test™, with the Food and Drug Administration (FDA) in USA. The decision follows a positive dialogue with FDA on factors involved in the decision to decline the company's previous application for approval, see company announcement no. 13 of May 28, 2016.

FDA approval is important for large-scale commercialization of The NGAL Test™ in the United States. FDA declined the previous application on grounds that it did not present adequate clinical and analytical data to support approval of the device, especially in mild cases of acute kidney injury. The Company expects to base the reapplication on new data to be collected as soon as possible.

Preparations for the reapplication initiates this summer. To manage the process, BioPorto hired Elisabeth Erhardtsen as VP Clinical and Regulatory Affairs. Elisabeth brings 23 years of international experience in clinical and regulatory affairs from Novo Nordisk, Baxter and Bayer. Elisabeth's track record is primarily related to the FDA and includes responsibility for approval of NovoSeven in the US for Novo Nordisk, while she at Bayer was responsible for the submission of a new factor IX product to the FDA.

Peter M. Eriksen, CEO of BioPorto, states: "We remain convinced of NGAL's potential. Clinical expert leaders in USA have confirmed their interest in improved diagnostics of acute kidney injury. They are supporting BioPorto's reapplication process for NGAL with FDA. Our newly incorporated US subsidiary with professionally competent employees with extensive FDA experience ensures a significantly improved platform for establishing future business. Consequently, and following discussions with both the FDA and external consultants, we have assessed that reapplication has substantial probability for approval. We expect to obtain approval within 18-24 months. "

The Company's financial outlook for 2016 is maintained.

**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 which 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.*