PRESS RELEASE
Copenhagen, June 6, 2016

Clinical Leaders Reinforce Belief in NGAL for Detection of AKI Following FDA's Decision on BioPorto's The NGAL Test™

In response to the recent FDA decision to decline BioPorto's initial submission for the kidney biomarker neutrophil gelatinase-associated lipocalin (NGAL) as the first diagnostic aid for acute kidney injury (AKI), several clinical leaders have reinforced their belief in the value of NGAL based on the data available.

Dr. Prasad Devarajan, Director of the Division of Nephrology and Hypertension said "At Cincinnati Children's Hospital we firmly believe that the implementation of NGAL as an early predictive biomarker of AKI severity after cardiopulmonary bypass surgery in our pediatric patients has significant clinical impact. Our belief in the clinical value of NGAL is based on several clinical studies done at our hospital showing the positive impact of diagnosis performed at the onset of AKI."

"In emergency room (ER) settings, the diagnosis of sustained AKI is difficult; mainly due to the wide range of causes for serum creatinine elevations in these patients.", said Dr. Jonathan Barasch, Columbia University Medical Center. "The use of NGAL in patients with elevated serum creatinine levels provides valuable clinical information to identify patients more likely to have sustained AKI, which is associated with worsening outcomes such as dialysis or death."

Peter McCullough, Cardiologist at the Baylor Heart and Vascular Institute, Baylor University Medical Center said, "The incorporation of a structural biomarker indicating active kidney damage such as NGAL will greatly enhance our understanding of AKI/CKD and allow us to devise prevention and management strategies."

"BioPorto is highly confident in the clinical value of NGAL, based on a large number of studies and scientific articles from both the USA and Europe, and we remain committed to bringing this important test to the US clinical market. We will meet with the FDA and clinical advisors in the coming weeks to develop a plan that meets the requirements for a successful FDA submission", says BioPorto CEO Peter Eriksen.

About AKI
AKI is a common, serious complication with severe outcomes for patients. The development of AKI leads to increased hospital stays, increased mortality and in severe cases, progression to dialysis. Current diagnostic biomarkers can take up to two days to become positive which results in a diagnostic gap in the first hours after kidney injury, when renal damage may be reversible. Consequently, there is a clinical need for the introduction of an early AKI biomarker like The NGAL Test™ as an additional diagnostic tool, for identification of sustained AKI. Clinical studies have shown that NGAL can rise as early as two hours after an AKI which provides the clinician additional information to use in stratifying patients for early and aggressive treatment.

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.

For further information, please contact:
Peter Mørch Eriksen, CEO
Telephone +45 4529 0000, e-mail investor@bioporto.com

BioPorto A/S • Tuborg Havnevej 15 st. • 2900 Hellerup • Denmark • info@bioporto.com • www.bioporto.com
Phone: +45 45 29 00 00 • CVR & Vat. No. DK-17 50 03 17