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Announcement no. 13

Progress in clinical trials for the FDA application for The NGAL Test™ and launch of new generic strip test

BioPorto has conducted a preliminary internal assessment of the data from the completed clinical trials in the USA. These data form the basis of the registration application to the FDA for approval of The NGAL Test™. The preliminary internal assessment of data support the further application process, including the formulation of the application, which is expected to be submitted to the FDA in September 2015 at the latest.

The antibody portfolio is extended with a generic strip test under the name gRAD (Generic Rapid Assay Device). gRAD is a patented lateral flow test system that allows the R&D segment to develop and apply qualitative and quantitative rapid tests for the detection of, among other, viruses and bacteria in research and veterinary use. BioPorto has in licensed the test as it is a good match for the portfolio of antibodies. The launch of the test does not affect the outlook for 2015, but is expected to become a significant product in the AntibodyShop portfolio over time.

Peter Mørch Eriksen, CEO, comments: "We are obviously pleased that the process regarding The NGAL Test™ in the US is in progress and that we are on-track with the application to the FDA. We therefore continue identifying and evaluating the strategic opportunities for successful market entry in the US. Similarly positive is that we continue to strengthen the antibody portfolio - this time with the new gRAD test, which has an interesting potential and is ideal to use with our antibodies. We expect that the test will attract new customers to our webshop and increase the sales of antibodies as well. "

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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.