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Announcement no. 07

First patient recruited for The NGAL Test™ clinical study in the US.

Today, the clinical study that forms the basis for BioPorto's FDA application for The NGAL Test ™, has commenced with recruitment of the first patients. Overall, 530 patients at approximately 20 US hospitals will be recruited.

After constructive discussions with the FDA on the protocol and great interest from participating hospitals, the initial recruitment and thus the official start of the study, has taken place on schedule.

Completion of the clinical study will lead to the submission of the final registration application to the FDA in 2018. Assuming a normal review process, BioPorto expects to receive FDA approval mid-2018 and thereafter will initiate commercialization of The NGAL Test ™ into the world's largest diagnostic market.

Peter Morch Eriksen says: "We have been focused and worked hard to initiate this clinical study on time and I'm glad to see that these efforts have been successful. We must now focus on completing the patient recruitment so data can be finalized and a registration application can be submitted to the FDA in accordance with BioPorto's announced timeline."

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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.