June 23, 2020
News release

BioPorto Initiates Patient Enrollment for US Pediatric Study of The NGAL Test™ with a Planned FDA Submission in the Second Half of 2020

First patients enrolled at Cincinnati Children's Hospital, a leading US center for critical care nephrology

June 23, 2020, Copenhagen: BioPorto announces the enrollment of the first patients in its prospective observational clinical study designed to verify and validate the performance of The NGAL Test™ for the risk assessment of moderate to severe acute kidney injury (AKI) in critically ill children.

The study initiation had been delayed by the global outbreak of COVID-19, which paused all non-critical clinical studies across the world. As hospital restrictions are gradually lifting across the US, BioPorto reiterates its expectations of completing the trial and filing the submission in the second half of 2020.

"We are excited to begin patient enrollment for this important trial in support of the company's foremost 2020 goal, which is to submit the pediatric De Novo to the FDA," said Christopher Bird, DPhil, Chief Medical Officer of BioPorto. "Since the delays caused by COVID-19, we have engaged in further collaborative discussions with FDA and are enthusiastic about our group of expert clinical collaborators. Initiating this study marks a critical step in bringing The NGAL Test to the US market," he explained.

The trial's Principal Investigator (PI), Stuart L. Goldstein, MD, FAAP, FASN, FNKF, Director, Center for Acute Care Nephrology at Cincinnati Children's Hospital Medical Center, an AKI expert, is coordinating the trial across ten leading pediatric US hospitals. Dr. Goldstein commented, "The NGAL Test will be an important new tool for clinicians caring for children at risk for clinically significant AKI, offering insights beyond what is available today. We are grateful to have engaged a leading group of pediatric clinician researchers and hospitals and are eager to kick-off this important work."

As expectations for the pediatric submission are unchanged, BioPorto maintains its guidance for 2020, as most recently described in its Interim Report for the first quarter of 2020.

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About BioPorto
BioPorto is an in vitro diagnostics company that provides tests and antibodies to clinicians and researchers around the world. We use our antibody and assay expertise to transform novel research tools into clinically actionable biomarkers that can make a difference in patients' lives. BioPorto is headquartered in Hellerup, Denmark and is listed on the NASDAQ Copenhagen stock exchange [CPH:BIOPOR].