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Announcement no. 19

Update on Patient Enrollment for Pivotal Study of NGAL in Pediatrics

COVID-19 has continued to impact hospital operations and BioPorto's enrollment of pediatric patients to be evaluated for moderate to severe acute kidney injury (AKI).

With the goal of optimizing the ongoing pediatric clinical trial's statistical power for the upcoming submission to the US Food and Drug Administration (FDA), BioPorto A/S (BioPorto) has decided to continue patient enrollment beyond its original goal of December 31, 2021, into the first half of 2022.

"Despite our strong focus on engaging with the participating clinics, enrollment has been slower than planned as COVID-19 still affects the health care sector. Based on actual enrollment figures and the outlook on COVID-19, we have revised our enrollment forecast and now expect to finish data collection in the first half of 2022," said Christopher Bird, Chief Medical Officer at BioPorto.

After enrollment is complete, BioPorto will continue to work interactively with the FDA to submit a De Novo Classification Request, as the NGAL Test maintains its Breakthrough Designation status.

This announcement does not alter BioPorto's financial guidance for 2021 as most recently presented in the Interim Report for Second Quarter 2021.

For further information, please contact:

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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].