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Announcement no. 15

BioPorto Successfully Completes Interim Analysis of Data from Pivotal Study of NGAL in Pediatrics with Encouraging Results

BioPorto A/S (BioPorto) has successfully concluded an interim analysis of data from the pediatric clinical trial being conducting to evaluate The NGAL Test™ as a tool for risk assessment of moderate to severe acute kidney injury (AKI). The study is being conducted to support a regulatory submission to the US Food and Drug Administration (FDA) and is being led by renowned pediatric critical care nephrologist, Dr. Stuart Goldstein of Cincinnati Children’s Hospital. The interim analysis includes data collected from six different leading US children’s hospitals over a twelve-month period.

BioPorto’s Chief Medical Officer, Dr. Chris Bird, commented, “We are encouraged with the results from our interim analysis for the clinical performance of the assay, including key characteristics such as sensitivity and specificity. We believe that, at the conclusion of our study, the final results will provide strong support for the value of The NGAL Test as a biomarker to identify risk of AKI in critically ill children.”

Following this interim analysis, BioPorto intends to continue expanding patient enrollment in order to maximize the study’s statistical power for the upcoming FDA submission. In the coming weeks BioPorto will evaluate additional study sites with the intention of expanding from the current 12 sites to up to 15 different partner hospitals. Based on the patterns of enrollment and prevalence of AKI in the initial data set, the company expects that it will complete the trial by the end of 2021, after which it will submit a De Novo Classification Request to the FDA. The NGAL Test maintains its Breakthrough Designation status and will continue to work interactively with the FDA.

The findings from the interim results do not alter BioPorto’s financial guidance for 2021 as most recently presented in the Interim Report for Second Quarter 2021.

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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].