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Announcement no. 23

In an effort to prioritize Emergency Use Authorizations (EUA), the FDA does not recommend that BioPorto pursue an EUA for its NGAL assay for the prediction of renal replacement therapy in COVID-19 patients

In July 2021, BioPorto A/S (BioPorto) initiated a dialogue with the US Food and Drug Administration (FDA) on a potential Emergency Use Authorization (EUA) of an NGAL assay for use in predicting the need for renal replacement therapy in COVID-19 patients. The dialogue was based on results from an ELISA and dipstick study of NGAL to screen for renal failure in COVID-19 patients conducted by clinical researchers at Columbia University's Irving Medical Center, reporting a 97% negative predictive value for the need of renal replacement therapy.

This week, the FDA provided guidance to all In-vitro Diagnostics manufacturers that the FDA will focus its reviews on at-home and point-of-care COVID-19 diagnostic tests, certain high-volume lab-based molecular COVID-19 tests from home collected specimens, and requests supported by US government stakeholders. Consistent with this communication, the FDA has informed BioPorto that it does not recommend submitting an EUA application. Based on this feedback, BioPorto has decided not to pursue an EUA for an NGAL assay with this application for COVID-19 patients.

"With the exciting data from Columbia University, we saw an interesting opportunity to use the study as a foundation for an EUA of an NGAL assay in screening patients for the need of renal replacement therapy in COVID-19 patients. As the FDA has now decided to prioritize other areas within COVID-19, we have decided to discontinue this path," said Dr. Christopher Bird, Chief Medical Officer at BioPorto.

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