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Announcement no. 3

Pipeline Update from BioPorto

- **BioPorto expects to complete its clinical study and submit a De Novo application to the FDA for pediatric use of The NGAL Test™ this summer.**
- **BioPorto awaits US test results for the rapid gRAD-based SARS-CoV-2 assay; if positive, the Company will proceed towards EUA and CE mark in the second quarter of 2021.**

In 2020, BioPorto A/S (BioPorto) began enrolling in a US clinical study for pediatric use of The NGAL Test for the risk assessment of acute kidney injury (AKI). The Company also undertook development of a novel SARS-CoV-2 viral test based on BioPorto's Generic Rapid Assay Device (gRAD) platform.

US application for The NGAL Test for pediatric AKI expected this summer

BioPorto's studies of The NGAL Test that don't require hospital enrollment are being finalized according to schedule. However, the study of critically ill (hospitalized) pediatric patients continues slowly due to delays caused by the second and third waves of the COVID-19 pandemic.

As of the beginning of March 2021, eight US hospitals have successfully been recruited to participate in the pediatric trial of NGAL, and BioPorto is continuing to add new sites to boost enrollment. Subject to further changes brought about by COVID-19, the Company expects to complete its pivotal study this summer and submit a De Novo 510(k) application to the US Food and Drug Administration (FDA).

Test results for gRAD-based SARS-CoV-2 test are pending

Based on the gRAD platform, BioPorto has developed a point-of-care test for SARS-CoV-2 designed to quickly and easily identify infected patients using a non-invasive sample. In late December 2020, BioPorto provided its first kits to the University of California, Davis (US) for testing with samples from COVID-19 patients.

After encountering initial issues in the trial, development teams on both sides of the Atlantic have worked together to resolve the challenges and BioPorto is currently awaiting outcome of the new testing. If results support BioPorto's laboratory findings, the Company will progress with plans to submit an Emergency Use Authorization (EUA) request with the FDA and a CE mark filing in Europe in the second quarter of 2021. To further support the CE mark application, BioPorto is also evaluating options for conducting additional testing at clinical sites in Europe.

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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].