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BioPorto plans initial clinical evaluation of gRAD-based test for rapid detection of COVID-19 virus

Development of a rapid point-of-care test for COVID-19 advances towards goal of requesting EUA and CE Mark in 2020

BioPorto Diagnostics A/S (BioPorto) and the University of Southern Denmark (SDU) announced in April 2020 a fast-track collaboration to create a rapid test for SARS-CoV-2, the virus that causes COVID-19. Leveraging SDU's antibody expertise and BioPorto's Generic Rapid Assay Device (gRAD) platform for the development of lateral flow assays, the collaboration envisioned developing an instrument-free, simple solution to test patients for SARS-CoV-2. Designed to provide a qualitative result in under 10 minutes from a minimally invasive sample, and to be easily administered at the point of care, the test could provide a much-needed solution to help improve access to viral testing.

Preliminary analytical studies of the newly created SARS-CoV-2 antibodies, for the detection of the active virus, have shown promising results in testing against heat-inactivated virus. These antibodies are highly specific to the virus's spike protein, which should potentially result in a higher clinical specificity when compared to other commercially available rapid tests. In continued development over the next several months, BioPorto plans to evaluate, optimize, and validate the test using a variety of different sample types from known-positive patients. If these efforts are ultimately successful, the Company intends to request an Emergency Use Authorization (EUA) from the US Food and Drug Administration (FDA) and to apply for CE Mark, which could lead to product launch before the end of the year.

"The expedited development of a gRAD-based COVID-19 test and our promising analytical results have been very encouraging," said Peter Mørch Eriksen, CEO of BioPorto. "In a short time, we have been able to develop a test and bring it to the clinical evaluation stage. If we achieve our goals, the new COVID test, for the detection of the active virus, will demonstrate the value of our gRAD platform for fast and flexible creation of lateral flow assays, but more importantly, it could help make a real difference in global efforts to slow the virus through broad-based testing."

The content of this announcement does not alter BioPorto's financial guidance for 2020 as most recently presented in the Interim Report for the first half of 2020.

For further information, please contact:
Peter Mørch Eriksen, CEO BioPorto Diagnostics A/S or
Jan Kuhlmann, PhD, COO BioPorto Diagnostics A/S
Telephone + 45 4529 0000, email investor@bioporto.com

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].