December 30, 2020
Announcement no. 22

BioPorto announces CE mark of near-patient test for kidney injury and milestones for gRAD platform technology

- **BioPorto has obtained CE marking in the EU for its NGALds, a novel gRAD-based test for near-patient measurement of NGAL, and announces commercial launch**
- **Its novel SARS-CoV-2 rapid test, also based on the gRAD-platform, is undergoing clinical testing at the University of California, Davis**
- **These two achievements mark significant product milestones for the Company's proprietary gRAD platform**

BioPorto Diagnostics A/S (BioPorto) announces the self-declaration (CE mark) in Europe of the NGALds, BioPorto's first test based on its proprietary Generic Rapid Assay Device (gRAD) platform for the development of lateral flow assays.

The NGALds is designed to deliver a semi-quantitative NGAL result in under 15 minutes, without the need for laboratory instrumentation or complex user training. This makes it ideal for near-patient settings such as physician offices and urgent care clinics, where a quick assessment of the risk of kidney injury can help clinicians to better triage patients. As an outpatient test, it will complement in-patient hospital use of BioPorto's automated assay, The NGAL Test™.

"I am very pleased with the rapid progress of NGALds, and of bringing the first test developed with our gRAD platform to market. As the first in a series of gRAD-based tests that we are creating, including tests for SARS-CoV-2 (COVID-19) and sepsis, it highlights the capabilities of gRAD. It also reinforces our focus on kidney disease, emphasizing the versatility of our NGAL technology and our commitment to improving kidney health through better diagnostics," said Peter Mørch Eriksen, CEO of BioPorto.

The commercial launch of the NGALds test will be initiated immediately in Europe through BioPorto's distribution partners and the company's sales team. At a later stage, BioPorto plans to seek regulatory approval of the test in other markets.

SARS-CoV-2 point-of-care test has been completed and advanced for clinical testing
In parallel with the development of NGALds, BioPorto implemented an accelerated gRAD development process to create a rapid test for the SARS-CoV-2 virus. The goal is to offer a simple test that can quickly and accurately identify infected patients using a non-invasive sample, delivering a result in under 15 minutes, at a price significantly less than molecular tests.

After completing successful antibody pairing, device prototyping and production agreements, on December 23rd, BioPorto provided test kits to the University of California, Davis (US) to test samples from approximately 150 COVID-19 patients.

Results are expected in early 2021; if positive, BioPorto plans to proceed with steps to submit an Emergency Use Authorization (EUA) request to the US Food and Drug Administration (FDA) and a CE mark filing in the EU for the COVID-19, gRAD-based test.

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

For further information, please contact:

Peter Mørch Eriksen, CEO
Telephone +45 4529 0000, e-mail: 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].