Amplidiag® COVID-19 molecular diagnostic test granted emergency use authorization in Finland for novel coronavirus

- Real-time PCR-based test enables high-throughput reliable detection of early COVID-19 infections for rapid isolation and treatment guidance

- Currently set up for routine use in main Finnish clinical labs with capacity to test up to 4,000 samples per day

FINLAND, Espoo, April, 14th, 2020 – Mobidiag Ltd. today announces that it has received emergency use authorization in Finland for its Amplidiag® COVID-19 molecular diagnostic test for the rapid detection of the SARS-CoV-2 virus, responsible for novel coronavirus infection (COVID-19). The Amplidiag® COVID-19 is now available for use in Finland*. The test will be run for routine use at the main clinical laboratories in Finland (Helsinki University Hospital (Huslab), SYNLAB and Mehiläinen) doubling Finnish testing capacity and allowing testing coverage for most of the country. The process for obtaining emergency use authorization is now ongoing in Sweden, UK and France. Mobidiag will register this test for CE-IVD mark and it should be available for widespread use in Europe in the coming weeks through Mobidiag's sales teams and local distributors.

The Amplidiag® COVID-19 assay allows qualitative determination of SARS-CoV-2 (orf1ab and N genes) from nasopharyngeal swabs. The test runs on Mobidiag's Amplidiag® Easy platform, which enables to clinicians an optimized sample screening process with automated DNA extraction and PCR plate setup. Based on well-established high-throughput PCR technology, it can process 48 samples in less than three hours.

In addition, Mobidiag is developing Novodiag® COVID-19, a molecular diagnostic test using its Novodiag® system for the rapid and on-demand detection of SARS-CoV-2. This test will complement Amplidiag® COVID-19 in enabling clinicians around the world to detect COVID-19 infections early, support decisions in managing efficiently epidemiological and infection control measures, isolate patients in a timely manner and improve patient care.

Tuomas Tenkanen, CEO of Mobidiag, said, "At Mobidiag, we recognize that we have a responsibility to support healthcare systems during this extraordinary situation and we are focusing our efforts in this endeavour. There is an urgent and growing need for reliable diagnostic solutions for the early detection of COVID-19, and Mobidiag has been able to leverage its capabilities and existing technologies to develop new diagnostic solutions quickly.

We are extremely pleased to bring our first diagnostic solution to the main clinical laboratories in Finland for large volume screening of COVID-19 and look forward to offering tests internationally in due course."

* Amplidiag® COVID-19 is now available in Finland as an emergency use test. Please note that Mobidiag tests are not home testing kits. They are only available for healthcare professionals, and not for patients directly. Please follow the recommended processes and guidance for your location if you believe you could be infected by SARS-CoV-2.

Contacts

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Notes to editors

About Mobidiag Ltd

Mobidiag is a commercial stage, fast growing molecular diagnostics company whose fast, cost-effective, widely applicable and robust technology makes the power of molecular diagnostics available to address the spread of infectious diseases and antimicrobial resistance (AMR) by rapid detection of pathogens and their potential resistance to antibiotics. Through its Amplidiag® and Novodiag® solutions, Mobidiag offers a comprehensive range of molecular diagnostic solutions for the detection of infectious diseases to laboratories of all sizes.

Mobidiag is headquartered in Espoo, Finland, with subsidiaries in France, UK and Sweden. To learn more, visit www.mobidiag.com