Biocartis Announces CE-marking of its Fully Automated Idylla™ SARS-CoV-2 Test

Mechelen, Belgium, 10 November 2020 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces to have launched the CE-marked IVD version of its fully automated Idylla™ SARS-CoV-2 Test. The test is intended to detect SARS-CoV-2, the virus that causes COVID-19, from nasopharyngeal swabs in viral transport medium, and runs on Biocartis' rapid and easy to use molecular diagnostics platform Idylla™.

The Idylla™ SARS-CoV-2 Test is a fully automated RT-PCR[1] test intended for the qualitative detection of
SARS-CoV-2 RNA[2] in nasopharyngeal swab specimens from individuals suspected of COVID-19 by their healthcare provider. Results are obtained using 200 µl of viral transport media in 90 minutes, with less than 2 minutes hands-on time. The test is performed by means of a single-use Idylla™ cartridge.

Herman Verrelst, Chief Executive Officer of Biocartis, stated*: "In a time where COVID-19 surges across many European countries, I am very proud of our team that worked hard to make this happen. This is our second CE-marked IVD infectious disease test offered this year on Idylla™, after the SeptiCyte© RAPID[3], which was released in Europe as a CE-IVD test early October. The Idylla™ SARS-CoV-2 Test is now available for clinical use across Europe to help healthcare providers manage this pandemic through rapid and easy testing of individuals with flu-like symptoms."*

The Idylla™ SARS-CoV-2 Test will be available across Europe, including use by Health Services Laboratories (HSL), a partnership between The Doctors Laboratory, Royal Free London NHS Foundation Trust (the Royal Free London), and University College London Hospitals NHS Foundation Trust (UCLH), one of the largest providers of highly specialized pathology and clinical laboratory services in the UK. HSL will be one of the first adopters of the Idylla™ SARS-CoV-2 Test.

Michael Gandy, Head of Research and Development for HSL, stated: "*We have been pleased to add Biocartis' Idylla™ platform to a number of other rapid diagnostic systems, with which we have undertaken performance evaluations prior to introduction in routine clinical practice. The performance characteristics of the Idylla™ SARS-CoV-2 Test have been comparable to our gold standard SARS-CoV-2 RT-PCR test offered from our central laboratory at the Halo building, London, and alongside the ease of use of the Idylla™ system, we feel this is an excellent candidate assay for provision of rapid testing in the acute setting*."

Dr. Rachael Liebmann, Group Medical Director for HSL and Vice President of the Royal College of Pathologists added: "*A further major benefit is that the Idylla™ platform is already deployed across a number of UK pathology laboratories performing oncology testing within cellular pathology. Therefore, there is a potential infrastructure readily available which can be used to support the COVID-19 effort across the UK."*

The US FDA 'Emergency Use Authorization' for the Idylla™ SARS-CoV-2 Test is still ongoing[4]. More information on the Idylla™ SARS-CoV-2 Test can be found here on the Biocartis website.