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Biocartis Announces Development of Idylla™ COVID-19 test

Mechelen, Belgium, 23 April 2020 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the development of a SARS-CoV-2 test, the virus that causes COVID-19, on the fully automated, rapid and easy to use molecular diagnostics platform Idylla™.

Upon regulatory approval, the Idylla™ SARS-CoV-2 test is targeted to help healthcare providers manage the COVID-19 pandemic through rapid and easy testing of individuals with flu-like symptoms. In addition, the Idylla™ SARS-CoV-2 test may be used in combination with the recently CE-marked IVD SeptiCyte® RAPID Test[1] on Idylla™ to facilitate the management of patients within the hospital intensive care unit (ICU). When used together, this combined testing solution on Idylla™ has the unique potential to identify patients with severe disease, as recent data[2] indicate that sepsis is the most frequently observed complication in COVID-19[3]. Biocartis develops the Idylla™ SARS-CoV-2 test with support from multiple undisclosed partners as part of a joint commitment to respond to the COVID-19 pandemic.

The Idylla™ SARS-CoV-2 test will be based on the Idylla™ Respiratory (IFV-RSV) Panel[4] that received 510(k) clearance by the US FDA on 5 September 2017 and is being designed to detect SARS-CoV-2 from respiratory samples such as nasopharyngeal swabs. Subject to a successful 'Emergency Use Authorization' by the US FDA, launch of the Idylla™ SARS-CoV-2 test is expected in the second half of 2020[5]. The US FDA 510(k) clearance of the SeptiCyte® RAPID Test on Idylla™ is expected along the same timelines.

The SeptiCyte® RAPID Test (CE-IVD) on Idylla™ is a rapid host-response[6] test, developed in collaboration with Immunexpress Pty Ltd ('Immunexpress'), that distinguishes sepsis from non-infectious SIRS (systemic inflammatory response syndrome) and provides actionable results in about one hour[7]. On 26 March 2020, Biocartis announced that it would lead the commercialization of this test in Europe as the exclusive distributor, while Immunexpress will lead commercialization in the US.

Herman Verrelst, Chief Executive Officer of Biocartis, commented: "*Developing a respiratory panel device detecting SARS-CoV-2 on Idylla™, especially when used in unique combination together with the Septicyte® RAPID Test on Idylla™, is expected to address the significant current and longer term unmet needs in hospitals and specifically in ICU's to more efficiently triage patients with flu-like symptoms. As such, unnecessary ICU admissions could potentially be prevented or average length of hospital stays could be reduced.*"

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1 Developed in collaboration with Immunexpress. More info here
2 Zhou et al., Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study, published online 9 March 2020, https://doi.org/10.1016/S0140-6736(20)30566-3
3 Sepsis developed at a median of 9 days (7–13) after illness onset among all patients, followed by ARDS (12 days [8–15]), acute cardiac injury (15 days [10–17]), acute kidney injury (15 days [13–19.5]), and secondary infection (17 days [13–9])
4 Legally acquired in 2018 from Janssen Diagnostics, a division of Janssen Pharmaceutica NV ('Janssen') who co-developed the assay Source: https://investors.biocartis.com/sites/default/files/press-releases/2019/170904-PR-510k-clearance-IFV-RSV-Panel-ENG.pdf
5 Subject to interactions with the US FDA
6 Host-response based tests focus on measuring biomarkers that are indicative of the response of a patient's immune system to an infection rather than measuring pathogens that are the cause of the infection
7 Moreover, SeptiCyte® RAPID not only discriminates sepsis from SIRS but also correlates with viral sepsis infection versus procalcitonin (PCT) which increases with severity of bacterial but not viral infection and is also a non-specific marker of inflammation

About Biocartis

Biocartis (Euronext Brussels: BCART) is an innovative molecular diagnostics (MDx) company providing next generation diagnostic solutions aimed at improving clinical practice for the benefit of patients, clinicians, payers and industry. Biocartis' proprietary MDx Idylla™ platform is a fully automated sample-to-result, real-time PCR (Polymerase Chain Reaction) system that offers accurate, highly reliable molecular information from virtually any biological sample in virtually any setting. Biocartis is developing and marketing a continuously expanding test menu addressing key unmet clinical needs, with a focus in oncology. This represents the fastest growing segment of the MDx market worldwide. Today, Biocartis offers tests supporting melanoma, colorectal and lung cancer. More information: www.biocartis.com. Follow us on Twitter: @Biocartis.

Forward-looking statements

Certain statements, beliefs and opinions in this press release are forward-looking, which reflect the Company's or, as appropriate, the Company directors' or managements' current expectations and projections concerning future events such as the Company's results of operations, financial condition, liquidity, performance, prospects, growth, strategies and the industry in which the Company operates. By their nature, forward-looking statements involve a number of risks, uncertainties, assumptions and other factors that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties, assumptions and factors could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward-looking statements contained in this press release regarding past trends or activities are not guarantees of future performance and should not be taken as a representation that such trends or activities will continue in the future. In addition, even if actual results or developments are consistent with the forward-looking statements contained in this press release, those results or developments may not be indicative of results or developments in future periods. No representations and warranties are made as to the accuracy or fairness of such forward-looking statements. As a result, the Company expressly disclaims any obligation or undertaking to release any updates or revisions to any forward-looking statements in this press release as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based, except if specifically required to do so by law or regulation. Neither the Company nor its advisers or representatives nor any of its subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this press release or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this press release.