



PRESS RELEASE

REGULATED INFORMATION

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Biocartis Announces Co-Commercialization of the SeptiCyte® RAPID Test on Idylla™ (CE-IVD) and Provides Update on COVID-19 Impact

Mechelen, Belgium, 26 March 2020 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the expansion of its partnership with Immunexpress Pty Ltd ('Immunexpress'), a Seattle-based molecular diagnostic company, with a co-commercialization agreement for the SeptiCyte® RAPID Test for use on Biocartis' fully automated molecular diagnostics platform Idylla™.

The SeptiCyte® RAPID Test is a rapid, host-response¹ test that distinguishes sepsis from infection negative systemic inflammation in patients suspected of sepsis and provides actionable results² in around one hour to guide the physician to optimize patient management decisions. Recent data³ indicate that sepsis is the most frequently observed complication in COVID-19⁴. In current COVID-19 pandemic times, hospitals and ICU's are under enormous pressure and SeptiCyte® RAPID could be a great support in detecting sepsis early on and supporting decisions for rapid initiation of sepsis management protocols in affected patients.

Biocartis and Immunexpress are strengthening their existing partnership⁵ with a co-commercialization agreement in which Biocartis will lead commercialization in Europe as the exclusive distributor of the SeptiCyte® RAPID Test, while Immunexpress will lead commercialization of the SeptiCyte® RAPID Test in the US. Immunexpress also announced today that the SeptiCyte® RAPID Test for use on the Idylla™ platform received CE-marking. Immunexpress expects US FDA 510(k) clearance by Q3 2020.

Herman Verrelst, Chief Executive Officer of Biocartis, commented: *"Deploying easy and rapid sepsis testing on Idylla™ with the CE-marked SeptiCyte® RAPID Test through our direct sales force in Europe can help preventing unnecessary ICU admissions or potentially even reducing average length of hospital stays – as such reducing the pressure on the hospital system, even after the immediate crisis is addressed. Although our focus remains in oncology, we currently see high unmet needs in the field of infectious diseases that we can help address with our Idylla™ platform. The expansion of our partnership with Immunexpress also allows us to make the necessary adjustments to minimize a potential impact on our business, linked to the disruptions in our commercial operations and the uncertainties caused in the market by the COVID-19 pandemic."*

Rolland D. Carlson, Ph.D., Chief Executive Officer of Immunexpress, reacted: *"I believe Biocartis, with its well established and growing Idylla™ customer base will be highly effective in delivering to the European community a new and novel sepsis diagnostic tool, designed to enhance the certainty of early and rapid sepsis diagnosis, to improve clinical outcomes and to lower healthcare costs. Together, we are committed to mitigating the constraints*

1 Host-response based tests focus on measuring biomarkers that are indicative of the response of a patient's immunesystem to an infection rather than measuring pathogens that are the cause of the infection

2 Moreover, SeptiCyte® RAPID not only discriminates sepsis from SIRS (Systemic inflammatory response syndrome) 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

3 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](https://doi.org/10.1016/S0140-6736(20)30566-3)

4 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])

5 On 24 January 2018, Biocartis and Immunexpress announced a partnership aimed at the development and commercialization of Immunexpress' SeptiCyte™ test for use on Biocartis' sample- to-result Idylla™ platform. Source: https://investors.biocartis.com/sites/default/files/press-releases/2019/180123-Press-release-partnership-IXP_EN.pdf

on hospitals that are affected by the COVID-19 pandemic, by more accurate diagnostic testing of sepsis, which is expected to enable physicians to make rapid clinical decisions in resource-constrained ICUs.”

In the context of the COVID-19 pandemic, Biocartis expects that the current prolonged measures taken in many countries across the globe to contain the spreading of COVID-19 may potentially impact the FY2020 outlook of the Company as announced in the [FY19 results and 2020 outlook](#) published on 5 March 2020, which initially assumed a normalization of activities around the April 2020 timeframe. The Company is monitoring the situation closely and will provide more information in due course. The Biocartis Q1 2020 Business Update is scheduled for 23 April 2020.

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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 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](https://twitter.com/Biocartis): @Biocartis.

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