PRESS RELEASE 30 November 2021, 17:40 CET

SeptiCyte® RAPID Receives 510(k) clearance by US FDA

Mechelen, Belgium, 30 November 2021 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces that the US Food and Drug Administration (FDA) has granted 510(k) clearance[1] for SeptiCyte® RAPID (CE-IVD, US FDA 510(k)). This test runs on Biocartis' rapid and easy-to-use molecular diagnostics Idylla™ platform[2] and was developed under Biocartis' partnership with Immunexpress Pty Ltd ('Immunexpress'), a Seattle-based molecular diagnostic company focused on improving outcomes for suspected sepsis patients.

Sepsis is the body's overwhelming and life-threatening response to infection which encompasses immune system dysregulation and can lead to tissue damage, organ failure, and death[3]. Today, diagnosing sepsis is challenging because conventional techniques such as blood culture or the detection of sepsis-related biomarkers such as lactate and procalcitonin are slow and often not very accurate[4]. At the time of treatment, physicians disagree on the right treatment in 40-60% of cases[5] because no accurate diagnostics are available to deliver a result at this time, which leads to the widespread overuse of antibiotics[3].

SeptiCyte® RAPID[6] is a fully automated, rapid host-response[7] test that distinguishes sepsis from infection negative systemic inflammation in patients suspected of sepsis. It provides actionable results[8] in about one hour, enabling physicians to optimize their patient management decisions.

Herman Verrelst, Chief Executive Officer of Biocartis, commented: "*We are proud of our partner to have achieved this milestone for the US market. Following the commercial launch of this test in Europe a year ago, the 510(k) clearance by the US FDA now enables the full commercial roll-out by Immunexpress in the US. This shows how our partners can really benefit from developing their test content on our decentralized Idylla™ platform. For Biocartis, the commercialization efforts in the US are expected to expand the US Idylla™ installed base and to strengthen cartridge volume growth.*"

"*The 510(k) clearance for SeptiCyte® RAPID comes at the right moment in the COVID-19 pandemic, specifically as winter approaches and various respiratory viruses proliferate. The burden of unceasing COVID-19 related hospitalizations emphasizes the importance of an early and accurate diagnosis of sepsis, especially in intensive care settings where quick action is needed. Moreover, our recent clinical validation study[9] demonstrates that SeptiCyte® RAPID continues to be more efficient and effective than traditional methods[10], which is needed now more than ever*," said **Rolland D. Carlson, Ph.D., Chief Executive Officer of Immunexpress.**

Immunexpress presented data supporting the use of SeptiCyte® RAPID for COVID-19 patient triage as an abstract at the 31st European Congress of Clinical Microbiology & Infectious Diseases (ECCMID), which took place virtually between 9-12 July 2021. More information on SeptiCyte® RAPID can be found on the Biocartis and Immunexpress website.

--- END ---

[1] Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance. This is known as Premarket Notification - also called PMN or 510(k)
[2] The Idylla™ Instrument and Idylla™ Console have been exempted by the US FDA since 12 July 2017 and as such are not subject to 510(k) notification requirements prior to being placed on the US market for *in vitro* diagnostic use with US FDA approved or cleared assays
[3] Sepsis Alliance, https://www.sepsis.org/, last consulted on 29 October 2021
[4] Source: https://septicyte.com/wp-content/uploads/2021/09/IMM-013-16x9-04-01-SC24-FINAL.pdf, last consulted on 29 October 2021
[5] Source: https://immunexpress.com/about-sepsis/, last consulted on 29 October 2021
[6] SeptiCyte® RAPID is developed by Immunexpress Inc in collaboration with Biocartis. Biocartis has the exclusive distribution rights for the EU. The test is not available in all countries. Availability to be checked with a local Biocartis representative
[7] 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
[8] 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
[9] Presented during the 2021 IDWeek Conference, taking place virtually from 29 September until 3 October 2021
[10] In a recent study presented by Immunexpress, superior performance of SeptiCyte® RAPID was demonstrated versus other frequently used clinical diagnostic tests including lactate and procalcitonin tests in differentiating sepsis from non-infectious inflammatory responses

More information:
Renate Degrave
Head of Corporate Communications & Investor Relations Biocartis
e-mail rdegrave@biocartis.com
tel +32 15 631 729
mobile +32 471 53 60 64
@Biocartis_ www.linkedin.com/Biocartis

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, which represents the fastest growing segment of the MDx market worldwide. Today, Biocartis offers tests supporting melanoma, colorectal and lung cancer, as well as for COVID-19, flu, RSV and sepsis. More information: www.biocartis.com. Follow us on Twitter: @Biocartis_.

About Immunexpress and SeptiCyte® RAPID
Immunexpress is a molecular diagnostic company, based out of Seattle, committed to improving outcomes for patients suspected of sepsis. Immunexpress' SeptiCyte® technology can assess a patient's dysregulated immune response by quantifying and analyzing gene expression from whole blood, providing actionable results in about an hour to guide the physician in optimizing patient management decisions. SeptiCyte® RAPID is a lab test for sepsis that combines SeptiCyte® technology with Biocartis' Idylla™ platform, empowering clinicians to swiftly differentiate infection positive (sepsis) from infection negative systemic inflammation in patients suspected of sepsis, diagnosing bacterial sepsis, viral sepsis, or fungal infections. This powerful combination of technologies enhances certainty for early sepsis diagnosis, to improve clinical outcomes and lower healthcare costs. More information can be found on the Biocartis and Immunexpress website.