

PRESS RELEASE

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Biocartis & Immunexpress Sign Partnership for a Sepsis Host Immune Response Test on the Idylla™ platform

Mechelen (Belgium)/Seattle (United States), 24 January 2018 – Biocartis Group NV ('Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART) and Immunexpress Pty Ltd ('Immunexpress'), a host response molecular diagnostic company, committed to improving clinical and economic outcomes for suspected sepsis patients, today announce that they have entered into a partnership agreement aimed at the development and commercialization of Immunexpress' SeptiCyte™ test for use on Biocartis' sample-to-result Idylla™ platform.

Immunexpress focusses on developing tests based on proprietary biomarker signatures that assess the response of a patient's immune system to infections. The SeptiCyte™ LAB, the first test from Immunexpress, recently received 510(k) clearance from the US FDA¹ for use on a manual PCR² instrument. The test aids in the differentiation of infection-positive (sepsis) from infection-negative (SIRS) systemic inflammation in critically ill patients on their first day of their admission in the ICU (intensive care unit).

Sepsis is a major unmet medical need caused by a patient's overwhelming and life-threatening immune response to infection and can lead to tissue damage, organ failure and death. Sepsis affects an estimated 20-30 million people worldwide³ every year. According to the Agency for Healthcare Research and Quality, sepsis is the most expensive condition treated in US hospitals, costing more than \$20 billion in 2011 and increasing annually on average by 11.9%⁴.

Time is a key element in the survival of a sepsis patient. Evidence shows that a delay in the treatment of a patient with sepsis increases mortality by 7.6% per hour in the first six hours⁵. Today's primary diagnostic approach for confirming a clinical diagnosis of sepsis is pathogen detection based on blood culture. This, however, has significant drawbacks: it can take several days before a result is obtained, the collection of the sample can result in false positives⁶ and most importantly, it only detects a pathogen in around 10% to 30% of suspected sepsis patients⁷.

Rob Lilley, Chairman at Immunexpress, stated: *"This partnership offers us the ideal marriage between the Idylla™ technology and the range of SeptiCyte™ host response tests. SeptiCyte™ can now be fully automated, allowing for fast near-patient testing, resulting in potentially life-saving clinical information. This will be very beneficial for all key healthcare stakeholders, including medical professionals, payers and patients."* **Roy Davis, MD, PhD, MHA Chief Medical Officer at Immunexpress, continued:** *"Sepsis is a true medical emergency. When recognized and treated early, lives are saved and costs are reduced. We look forward to working together with Biocartis, and to make a real difference with accessing timely clinical information with this SeptiCyte™ blood test for aiding in differentiating infection in 100% of suspected sepsis patients."*

Herman Verrelst, Chief Executive Officer at Biocartis, reacted: *"We are enthusiastic about our new partnership with Immunexpress, whose recent 510(k) clearance for its Immunexpress' SeptiCyte™ LAB test underlines the validation and quality of its approach. This test will definitely benefit from the unique features of our Idylla™ system, which allows results to be generated in a timeframe that supports the time-critical decision-making required in the management of sepsis patients. Furthermore, the knowledge and extensive network of Immunexpress within the field of sepsis is very impressive and complementary to ours, ensuring all fundamentals for a strong partnership."*

¹ US Food and Drug Administration.

² Polymerase Chain Reaction.

³ World Sepsis Day Factsheet 2014, available at www.world-sepsis-day.org.

⁴ Torio et al., "National Inpatient Hospital Costs: The Most Expensive Conditions by Payer", 2011: Statistical Brief #160. In: "Healthcare Cost and Utilization Project (HCUP) Statistical Briefs, Rockville (MD)": Agency for Health Care Policy and Research (US) 2006-2013.

⁵ Kumar et al. Crit Care Med. 2006 Jun; 34(6):1589-96.

⁶ Weinstein PM et al (2003) J Clin Microbiol 41(6):2275.

⁷ Coburn et al (2012) JAMA, August 2012, Vol 308, No.5

Under the partnership, parties will co-develop the SeptiCyt[™] Idylla[™] test, whereas Immunexpress will take the lead in the commercialization, with an initial focus on the US and the European markets. Financial details of the partnership are not disclosed.

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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 launched the Idylla[™] platform in 2014. Biocartis is developing and marketing a rapidly expanding test menu addressing key unmet clinical needs in oncology and infectious diseases. These areas represent respectively the fastest growing and largest segments of the MDx market worldwide. Today, Biocartis has twelve oncology tests and two infectious disease tests in its product menu. More information: www.biocartis.com. Press Photo Library available [here](#). Follow us on [@Biocartis_](https://twitter.com/Biocartis_).

About Immunexpress

Immunexpress is a Seattle-based molecular diagnostic company committed to improving outcomes for patients suspected of sepsis. Immunexpress' SeptiCyt[™] technology rapidly quantifies, directly from whole blood, specific molecular markers from the patient's own immune system – the 'host response'. SeptiCyt[™] LAB, recently cleared by the FDA, is the first of its kind in using the host immune system to differentiate systemic inflammatory response syndrome (SIRS) and sepsis. Detecting the host's response to infection has the potential to differentiate infection earlier, faster and more accurately than finding the invading pathogen because it is independent of whether or not the pathogen is present in the sample. Immunexpress' pipeline includes several assays for readily available instruments, including random access, point-of-care (POC) and sample-to-answer.

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Forward-looking statements

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