





Press release

# Debiopharm, Immunexpress and Biocartis Announce Collaboration to Advance Development of SeptiCyte<sup>®</sup> Triage for Managing Sepsis

Lausanne, Switzerland and Brisbane, Australia, June 19, 2012 – Today, Debiopharm Group™ (Debiopharm), Immunexpress Group and Biocartis announced a world-wide exclusive, royalty-bearing license for the late-stage development and commercialization of SeptiCyte® Triage – a multiplex gene expression assay for use in Emergency and Intensive Care Units (ICUs) or upon hospital admission to diagnose sepsis early, differentiate sepsis from other forms of inflammation, and determine sepsis severity.

Under the terms of the agreement, Debiopharm will fund the validation and U.S. Food and Drug Administration (FDA) clearance of SeptiCyte® Triage and Biocartis will subsequently fund the development and commercialization of the validated SeptiCyte® Triage assay on its fully integrated molecular diagnostics platform. This platform – which includes an instrument, communication console, and single use, disposable cartridges – can detect and quantify multiple DNA- or RNA-based biomarkers in a wide variety of patient sample types with minimal user intervention in less than 90 minutes. As part of the agreement, Debiopharm will complete an equity investment in Immunexpress of AUD 2 million.

"The synergy created by this partnership is not only important for the continued development and future availability of SeptiCyte®Triage – but it also exemplifies Immunexpress' commitment to innovative science and partnerships that improve outcomes for clinicians and patients", said Dr Roslyn Brandon, President and CEO, Immunexpress. "With accuracy significantly better than procalcitonin, bringing SeptiCyte® Triage onto Biocartis' revolutionary point-of-need multiplex qRT-PCR platform will enable clinicians to more quickly and accurately identify and triage patients suspected of sepsis».

Greg Parekh, Biocartis' CEO, commented: "Biocartis is striving to bring more effective, individualized treatments within reach of patients through the availability of high quality diagnostics at the point of need. Sepsis is a major cause of death where timely accurate diagnostic information can make a significant difference in medical outcomes".

"Debiopharm is enthusiastic to join forces with Immunexpress and Biocartis and to take an additional step in our strong commitment to personalized medicine", said Thierry Mauvernay, Debiopharm's delegate of the board, who added, "The collaboration opens the door to exploit synergies between the three companies by addressing this life-threatening condition from different perspectives, particularly from a health economics one. Supporting better management of sepsis may ultimately lead to a reduction in mortality, better outcomes and possibly the discovery of new therapies".

#### **About Debiopharm Group**

Debiopharm Group<sup>™</sup> (Debiopharm) is a Swiss-based global biopharmaceutical group of companies with a focus on the development of prescription drugs that target unmet medical needs. The group inlicenses, develops and/or co-develops promising biological and small molecule drug candidates having reached clinical development phases I, II or III, as well as earlier stage candidates. It develops

its products for global registration and maximum commercial potential. The products are out-licensed to pharmaceutical partners for sales and marketing. Debiopharm is also active in the field of companion diagnostics with a view to progressing in the area of personalized medicine. Debiopharm independently funds the worldwide development of all of its products while providing expertise in preclinical and clinical trials, manufacturing, drug delivery and formulation, and regulatory affairs. For more information on Debiopharm Group™, please visit: www.debiopharm.com.

### **About Sepsis**

Sepsis, a life-threatening generalized inflammation from infection, is the leading cause of death in ICUs worldwide and increasing in incidence. It is widely known that early diagnosis and early, targeted treatment improve survival; however, today's diagnostics are pathogen-focused, insensitive (with a 30-50% failure rate), and slow (taking more than 24 hrs for test results). With currently available testing, it is also difficult for clinicians to distinguish sepsis from Systemic Inflammatory Response Syndrome (SIRS) – an inflammatory state affecting the whole body that presents very much like sepsis, but is not caused by infection.

Worldwide, there are 18 million cases of diagnosed sepsis per year and the incidence is rising at 8 to 10 percent annually; in the developed world, an estimated 1,400 patients die from sepsis each day (~ 511,000 each year). New technologies to allow for earlier detection and personalized management of patients with, or at risk of, sepsis could significantly reduce the financial burden on healthcare systems worldwide through reduced patient mortality; fewer missed cases in the emergency setting; reduced stays in ICU; more targeted use of antibiotics and anti-inflammatories; reduced antimicrobial resistance; and reduced at-risk admissions. Patients at risk of sepsis include infants, mothers after childbirth, the elderly, those with weakened immune systems or those who have experienced significant trauma/injury, invasive surgery, or burns. However, healthy people can also develop and become ill from sepsis.

## About SeptiCyte® Technology

The Immunexpress first-in-class SeptiCyte® technology quantifies specific and multiple molecular markers from the patient's own immune system ('host response') for earlier detection, severity assessment, and better timing and targeting of drug and other therapies. Results from Immunexpress clinical trials show that biomarkers of the patient's immune response are more accurate and instructive than pathogen detection for early detection and improved management of sepsis. By translating and quantifying complex molecular signals in an objective score, SeptiCyte® technology provides reports on disease probabilities – enabling clinicians to better manage sepsis patients for improved patient outcomes. The SeptiCyte® technology is the basis for three products – SeptiCyte® Triage, SeptiCyte® STAT, and SeptiCyte® RTT – which are intended for use on the Biocartis platform in a variety of critical care hospital settings, but will also be available for other standard hospital laboratory platforms.

#### **About Immunexpress Group**

Immunexpress is a molecular diagnostic company committed to improving outcomes for patients with, or at risk of, sepsis. Immunexpress' core competency is the discovery and clinical validation of genomic and proteomic biomarkers, and the translation of these novel biomarkers into clinical diagnostic and monitoring assays for readily available platforms, including point-of-care (POC). Immunexpress is a privately-held group of companies with locations in Brisbane, Australia and Seattle, USA. For more information about Immunexpress, please visit: www.Immunexpress.com.

## **About Biocartis**

Biocartis aims to improve healthcare outcomes by enabling the practice of personalized medicine anywhere, anytime. Biocartis' ambition is to establish a new gold standard in diagnostic testing. Biocartis is currently developing innovative diagnostic systems with following key features: fully automated, simultaneous detection of many biomarkers, fast, simplified workflow and minimal hands on time, integrated sample preparation for a broad range of sample types.

Biocartis develops assays which have high clinical utility and compelling health economic value. Biocartis' broad platform capabilities are well suited to address the growing need for individualized diagnosis and treatment of patients. Biocartis welcomes collaborations with assay development companies world-wide to enable new In Vitro Diagnostic Multivariate Index Assays on its revolutionary platform.

Biocartis follows a unique alliance model which leverages the combined resources of its current alliance partners (bioMérieux and Janssen Diagnostics) and future alliance members to jointly and efficiently install and service a global base of instruments and develop a broad menu of diagnostic tests. Biocartis is a rapidly growing company; to date Biocartis staff includes over 120 people. The company has raised in total EUR 125 million in equity.

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