PRESS RELEASE 22 December 2016, 07:00 CET

Biocartis submits 510(k) file with US FDA for Idylla™ platform

Submission done in parallel with 510(k) submission of Janssen Idylla™ Respiratory (IFV-RSV) Panel Test by Janssen Diagnostics

Mechelen, Belgium, 22 December 2016 - Biocartis Group NV ('Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announced the 510(k) submission[1] to the U.S. Food and Drug Administration (FDA) of its rapid, fully automated molecular diagnostics platform Idylla™, consisting of the Idylla™ Instrument and the Idylla™ Console.

The submission was done in parallel with the 510(k) submission by Biocartis' strategic partner Janssen Diagnostics (a Janssen Pharmaceutical Company) of the Janssen Idylla™ Respiratory (IFV-RSV) Panel Test. This test, developed by Janssen Diagnostics on the Idylla™ platform, is intended for the detection of various strains of Influenza Virus (IFV) and Respiratory Syncytial Virus (RSV).

Following the announcement of Biocartis' partnership with Thermo Fisher Scientific Inc. on 17 November 2016, the 510(k) submission of its molecular diagnostics platform Idylla™ is another important milestone for Biocartis towards establishing a commercial presence in the US.

Rudi Pauwels, Chief Executive Officer of Biocartis, **commented**: "*This 510(k) submission was a joint effort between the teams of Janssen Diagnostics and Biocartis, and another great achievement resulting from the longstanding strategic partnership between both companies. The experience of the Janssen Diagnostics' team has been of much added value in preparing for this submission and we want to thank our partner for their continued commitment and support.*"

--- END ---

More information:
Renate Degrave
Manager Corporate Communications & Investor Relations
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 launched the Idylla™ platform in September 2014 in Europe. 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 offers six oncology tests and two infectious disease tests in Europe. More information: www.biocartis.com. Press Photo Library available here. Follow us on Twitter: @Biocartis_.

[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).

Certain statements, beliefs and opinions in this press release are forward-looking, which reflect the Company or, as appropriate, the Company directors' 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. As a result, the Company expressly disclaims any obligation or undertaking to release any update 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. 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.