PRESS RELEASE 12 July 2017, 07:00 CEST

Biocartis' Idylla™ Instrument and Idylla™ Console exempt from US FDA 510(k) notification requirements

Mechelen (Belgium), 12 July 2017 - Biocartis Group NV ('Biocartis' or the 'Company'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces that on 11 July 2017 the US FDA[1] published a final list of devices that it has exempted from 510(k) premarket notification requirements in accordance with the US 21st Century Cures Act (signed into US law 13 December 2016). The product codes applicable to the Biocartis Idylla™ Instrument and Idylla™ Console are included on this list. Consequently, Biocartis' Idylla™ Instrument and Idylla™ Console are no longer subject to 510(k) notification requirements prior to being placed on the US market for *in vitro* diagnostic use with FDA approved or cleared assays. All other US 510(k) requirements, including current Good Manufacturing Practices (cGMP) and vigilance reporting, remain in effect. With this exemption in place, Biocartis is complying with the instructions in the publication and can now withdraw the pending 510(k) submission for the Idylla™ Instrument and Idylla™ Console.

Vishal Sikri, General Manager of Biocartis US, reacted: *"The publication of this list by the US FDA will allow us to speed up the introduction of our fully automated Idylla™ platform in the US. This positive news is one more step towards our vision of bringing high value, rapid molecular diagnostic testing to hospitals in the US."*

Today's announced exemption does not change the ongoing undertaking of Biocartis and its strategic partner Janssen Diagnostics to obtain 510(k) clearance for the Janssen Idylla™ Respiratory (IFV-RSV) Panel test.

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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 September 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 offers ten oncology tests and two infectious disease tests in Europe. More information: www.biocartis.com. Press Photo Library available here. Follow us on Twitter: @Biocartis_.

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[1] US Food and Drug Administration.

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