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Idylla™ Respiratory (IFV-RSV) Panel receives 510(k) clearance by US FDA

First test cleared for use on the Idylla™ platform by US FDA

Mechelen, Belgium, 5 September 2017 – 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 the Idylla™ Respiratory (IFV-RSV) Panel, a fully automated molecular diagnostic test, developed by Janssen Diagnostics, a division of Janssen Pharmaceutica NV ('Janssen'). The Idylla™ Respiratory (IFV-RSV) Panel runs on the Biocartis Idylla™ platform.

Biocartis' strategic partner Janssen led the submission process of this premarket notification and developed the test intended for the detection of various strains of Influenza Virus (IFV) and Respiratory Syncytial Virus (RSV), using Biocartis' molecular diagnostics platform Idylla™. Thanks to the fully integrated workflow and ease-of-use of this platform, the Idylla™ Respiratory (IFV-RSV) Panel can be performed in approx. 50 minutes, requires less than two minutes hands-on time, and operates from nasopharyngeal swab[2] samples in viral transport media.

Erwin Sablon, Head of R&D and Alliance Management of Biocartis, commented: *"We want to congratulate our strategic partner Janssen for obtaining this US FDA clearance. This is an impressive achievement of both our teams. It also marks an important milestone for Biocartis, as this is the first US FDA cleared test on our Idylla™ platform, adding yet another layer of validation to the quality of our product offering."*

On 12 July 2017, Biocartis announced the exemption by the US FDA of its Idylla™ Instrument and Idylla™ Console, which are no longer 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. In Q3 2017, Biocartis launched the commercialization of its oncology menu (for research use only) in the US through its subsidiary, Biocartis Inc., and in collaboration with Thermo Fisher Scientific Inc.

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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_.

[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™ (Respiratory) IFV-RSV Panel is a single-use assay intended for the qualitative detection of nucleic acids of Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza A subtype 2009 H1, H275Y mutation of Influenza A subtype 2009 H1, Influenza B and Respiratory Syncytial Virus (A and B) from nasopharyngeal swabs (NPS) in viral transport media of adult and pediatric patients, using the Idylla™ molecular diagnostics platform to aid in the diagnosis of respiratory viral infection.

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Forward-looking statements
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