PRESS RELEASE 2 September 2021, 07:00 CEST

Biocartis Launches Idylla™ SARS-CoV-2/Flu/RSV Panel

Mechelen, Belgium, 2 September 2021 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the launch of its Idylla™ SARS-CoV-2/Flu/RSV Panel (CE-IVD). Building upon the success of its Idylla™ SARS-CoV-2 Test (CE-IVD), the new Panel is launching as a CE-IVD and detects, in one single cartridge, SARS-CoV-2, Flu A/B and RSV[1] nucleic acids, with results in approx. 90 minutes.

The Idylla™ SARS-CoV-2/Flu/RSV Panel is a fully automated rRT-PCR[2] test intended for the qualitative detection of SARS-CoV-2, Flu A/B and RSV nucleic acids in nasopharyngeal swab specimens from individuals suspected of respiratory infections by their healthcare provider. The nasopharyngeal swab specimens are collected in a viral transport medium[3] and can be pipetted directly into the cartridge. The Idylla™ SARS-CoV-2/Flu/RSV Panel includes fully automated nucleic acid testing with the extraction, amplification and detection in a single-use cartridge, with less than 1 minute hands-on time.

The Panel showed excellent performance in the clinical performance study[4] with 98% overall concordance compared with other currently used methods.

Commenting on the launch of the Idylla™ SARS-CoV-2/Flu/RSV Panel, Herman Verrelst, Chief Executive Officer of Biocartis, said: "*We take an important next step in strengthening our infectious disease menu by upgrading the Idylla™ SARS-CoV-2 Test[5] (CE-IVD) to a Panel that now also includes Flu A/B and RSV. Ahead of a delayed flu season, this Panel is well positioned to guide healthcare providers in this complex landscape of respiratory infections in 2022.*"

The timing of the Emergency Use Authorization ('EUA') submission to the US FDA of the Idylla™ SARS-CoV-2/Flu/RSV Panel is still to be decided.

--- END ---

More information:
Renate Degrave
Head of Corporate Communications & Investor Relations Biocartis
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 is developing and marketing a continuously expanding test menu addressing key unmet clinical needs, with a focus in oncology, which represents the fastest growing segment of the MDx market worldwide. Today, Biocartis offers tests supporting melanoma, colorectal and lung cancer, as well as for SARS-CoV-2/Flu/RSV and sepsis. More information: www.biocartis.com. Follow us on Twitter: @Biocartis_.

1 Respiratory Syncytial Virus
2 Real-Time Reverse Transcription-Polymerase Chain Reaction
3 Of which 400 µl VTM is used in Idylla™
4 Performance was evaluated across two arms of a clinical evaluation, all samples were residual nasopharyngeal swab in viral transport media. In the first arm 322 specimens were collected to evaluate the performance of the Idylla™ SARS-CoV-2/Flu/RSV Panel compared to the DiaSorin Molecular Simplexa™ Flu A/B & RSV Direct. In the second arm 341 specimens were collected to evaluate the performance of the Idylla™ SARS-CoV-2/Flu/RSV Panel compared to the Luminex Aries® SARS-COV-2 Assay. More information here
5 The Idylla™ SARS-CoV-2 Test (CE-IVD) will remain available

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. No representations and warranties are made as to the accuracy or fairness of such forward-looking statements. As a result, the Company expressly disclaims any obligation or undertaking to release any updates 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, except if specifically required to do so by law or regulation. 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.