



PRESS RELEASE

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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 RSV¹ nucleic acids, with results in approx. 90 minutes.

The Idylla™ SARS-CoV-2/Flu/RSV Panel is a fully automated rRT-PCR² 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 medium³ 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 study⁴ 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 Test⁵ (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.

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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 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](https://twitter.com/Biocartis): @Biocartis_.

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Forward-looking statements

Certain statements, beliefs and opinions in this press release are forward-looking, which reflect the Company's or, as appropriate, the Company directors' or managements' 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

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

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