



PRESS RELEASE

5 August 2019, 07:00 CEST  
(4 August 2019, 22:00 PDT)

## Study on Performance Data of Idylla™ NRAS-BRAF Mutation Assay at 71st AACC Annual Scientific Meeting in Anaheim, CA (US)

**Mechelen, Belgium, 5 August 2019** – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces that a study<sup>1</sup> poster on the performance of the Idylla™ NRAS-BRAF Mutation Assay (RUO<sup>2</sup>) will be presented by Dr. Gregory Tsongalis (Director, Laboratory for Clinical Genomics and Advanced Technology of the Dartmouth-Hitchcock Medical Center) at the 71st AACC (American Association for Clinical Chemistry) Annual Scientific Meeting taking place between 4-8 August in Anaheim, CA (US). The study concludes that the Idylla™ system offers rapid and accurate testing of NRAS and BRAF mutations in melanoma directly from FFPE<sup>3</sup> tissue, and that its simplicity and ease of use compared to other available molecular techniques make it suitable for small centers that lack specifically trained staff and infrastructure. Furthermore, the study concludes that the Idylla™ system can also complement NGS (Next-Generation Sequencing) by providing much faster turnaround times.

In the study, twenty-two archived FFPE melanoma tissue specimens were tested on the Idylla™ system using the Idylla™ NRAS-BRAF Mutation Assay (RUO). Among these samples, eight had a mutation in BRAF, six had a mutation in NRAS, and eight had no mutations in BRAF or NRAS as determined by previous NGS testing<sup>4</sup>. The Idylla™ system successfully detected mutations in BRAF and NRAS and results were in full agreement with those previously obtained by NGS. Idylla™ produced results quickly with a turnaround time of approximately two hours.

**Dr. Gregory Tsongalis, PhD, Director of the Laboratory for Clinical Genomics and Advanced Technology at Dartmouth-Hitchcock Medical Center, explains:** *"The Idylla™ system has the potential to play a significant role in rapid screening for actionable mutations prior to NGS analysis, also for small laboratory centers that lack staff with molecular diagnostics training and infrastructure."*

The poster will be presented on 7 August 2019 by Dr. Gregory Tsongalis, PhD, Director, Laboratory for Clinical Genomics and Advanced Technology at Dartmouth-Hitchcock Medical Center at the 71st AACC Annual Scientific Meeting in Anaheim, CA (US).

--- END ---

### More information:

Renate Degrave  
Head of Corporate Communications & Investor Relations  
e-mail [rdegrave@biocartis.com](mailto:rdegrave@biocartis.com)  
tel +32 15 631 729  
mobile +32 471 53 60 64

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

[www.linkedin.com/Biocartis](https://www.linkedin.com/Biocartis)

<sup>1</sup> M. Rabie Al-Turkmani et al., 'Evaluation of a Cartridge-Based System for Rapid Detection of BRAF and NRAS Mutations in Melanoma', Dartmouth-Hitchcock Medical Center and Geisel School of Medicine at Dartmouth, first published at the 71st AACC Annual scientific meeting & clinical lab expo, 4-8 August 2019, Anaheim (CA), US, available on <https://www.abstractsonline.com/pp8/#!/6831/presentation/566>.

<sup>2</sup> Research Use Only, not for use in diagnostic procedures.

<sup>3</sup> Formalin Fixed, Paraffin Embedded.

<sup>4</sup> Using the Ion AmpliSeq 50-gene Cancer Hotspot Panel v2 (Thermo Fisher Scientific).

## **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 in oncology. This area represents the fastest growing segment of the MDx market worldwide. Today, Biocartis offers tests supporting melanoma, colorectal and lung cancer. More information: [www.biocartis.com](http://www.biocartis.com). Press Photo Library available [here](#). Follow us on [Twitter](#): @Biocartis\_.

*Biocartis and Idylla™ are registered trademarks in Europe, the United States and other countries. The Biocartis and Idylla™ trademark and logo are used trademarks owned by Biocartis. This press release is not for distribution, directly or indirectly, in any jurisdiction where to do so would be unlawful. Any persons reading this press release should inform themselves of and observe any such restrictions. Biocartis takes no responsibility for any violation of any such restrictions by any person. Please refer to the product labeling for applicable intended uses for each individual Biocartis product. This press release does not constitute an offer or invitation for the sale or purchase of securities in any jurisdiction. No securities of Biocartis may be offered or sold in the United States of America absent registration with the United States Securities and Exchange Commission or an exemption from registration under the U.S. Securities Act of 1933, as amended.*

## **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 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.*