BIOCARTIS MEETS 2022 KEY OBJECTIVES

Mechelen, Belgium, 17 January 2023 - Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), announces that the Company has achieved its 2022 key business objectives focused on three performance indicators: Idylla™ product revenues, gross margins on product sales and operating cash burn.

Based on non-audited numbers for 2022, Biocartis today reports:

- Idylla[™] product revenues of EUR 45m are fully in line with the latest guidance and included EUR 35.8m from cartridge sales (+13% year-on-year) and EUR 9.2m from instrument sales and rentals (+4% year-on-year). Within cartridge sales, the core oncology business grew 30% year-on-year, while SARS-CoV-2 cartridge sales were 49% lower than in 2021 against the backdrop of fading COVID-19 testing needs.
- Gross margins on product sales of 34%, a strong increase from 16% in 2021 and well in excess of the guidance of at least 30%.
- Operating cash burn (EBITDA plus capital expenditure) of EUR 38.5m, significantly better than the previously expected range of EUR 41m 43m and a sizeable reduction of EUR 18.1m from EUR 56.6m in 2021.

Herman Verrelst, Chief Executive Officer of Biocartis, commented: "We are happy to report that we delivered on our 2022 outlook and managed to build strong foundations for further expansion, both operationally and financially, in challenging markets and an unstable economic climate. Operationally, we significantly increased our gross margins to 34% at year-end. We saw a solid increase in our Average Sales Price (ASP) as a result of continued strong growth of our oncology revenues and we benefited from increasing economies of scale thanks to the continued ramp up of our second fully automated cartridge manufacturing line. We further consolidated and grew our European oncology customer base, and signed new, important contracts in the US, now serving several of the top 10 US cancer centers with our rapid and easy Idylla™ products. We made important progress in the expansion of our global commercial footprint with the regulatory approval of the Idylla™ Instrument in China and a first CDx1 approval in Japan, for the Idylla™ MSI Test. Partnerships remain a key attribute in our strategy of rapidly expanding our test menu and making it available for any lab. In 2022, we signed a CDx partnership with respect to AstraZeneca's Tagrisso® and initiated the commercialization of partners tests with the Merlin kit (SkylineDx) in melanoma and HepatoPredict (Ophiomics) in liver cancer. Finally, we now fully completed the comprehensive recapitalization that provided for EUR 66m of gross new money and structurally strengthens our capital structure. Also, in Q4, we decided to streamline our organization to withstand the ongoing pressure from cost inflation. We are confident that we will continue to grow and further reduce the cash burn in 2023, on our way to profitability."

In 2022, Biocartis made significant progress both on operational, commercial and financial level to secure its next level of expansion. Achievements included the following:

- In February 2022, Biocartis announced a new partnership with Ophiomics² for the commercialization of HepatoPredict, a prognostic gene expression signature test to help identify which patients with Hepatocellular Carcinoma (HCC) will benefit from curative-intent surgery, in particular liver transplantation. In October 2022, Biocartis started the commercialization of the HepatoPredict test (developed by Ophiomics) as a CE-IVD marked prognostic diagnostic manual kit that supports the decision of liver transplantation in patients.
- In June 2022, Biocartis announced a double milestone with the selling of its one-millionth commercial Idylla™ cartridge and the placement of its 2,000th Idylla™ instrument since its commercial launch.
- Also in <u>June 2022</u>, Biocartis launched its CE-marked, fully automated <u>Idylla™</u> <u>GeneFusion Panel</u> (CE-IVD) which detects in one single cartridge ALK, ROS1, RET and

METex14 skipping, a wide range of actionable targets for fast treatment decisions in non-small cell lung cancer (NSCLC).

- End of <u>June 2022</u>, Biocartis announced a new partnership agreement with AstraZeneca (LSE/STO/Nasdaq: AZN) aimed at the development and applicable pre-market notification with the US FDA of a novel CDx test on the Idylla™ platform, for use with Tagrisso® (osimertinib³).
- In <u>September 2022</u>, Biocartis announced the start of the commercialization in Europe of <u>SkylineDx's</u> innovative <u>Merlin Assay</u> as a CE-IVD marked manual kit aiming to predict a melanoma patient's risk of nodal metastasis and may help safely forgo an invasive surgery.
- Also in <u>September 2022</u>, Biocartis announced its comprehensive recapitalization transaction aimed at securing adequate capital to support the Company's growth for the foreseeable future.

Additionally, in 2022, a record of 42 new publications on Idylla[™] products were issued by key opinion leaders across the globe validating the high performance of Idylla[™] products, bringing the total number of Idylla[™] publications to 166 end of 2022. Publications included several studies with Idylla[™] tests such as the <u>Idylla[™] EGFR Mutation Test</u> (CE-IVD) and the <u>Idylla[™] GeneFusion Panel</u> (CE-IVD) for non-small cell lung cancer (NSCLC), as well as a new, large prospective study demonstrating that the Idylla[™] EGFR Mutation Test (CE-IVD) leads to the significant reduction of the time-to-treatment by 48% or on average 16.8 days faster than Next Generation Sequencing (NGS) testing for EGFR positive patients. This shows Idylla[™]'s potential to improve strategic treatment decisions within a multidisciplinary team for patients with advanced NSCLC.

Biocartis will publish its 2022 full year results and 2023 guidance on 23 February 2023.

---- 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

About Biocartis

With its revolutionary and proprietary IdyllaTM platform, Biocartis (Euronext Brussels: BCART) aspires to enable personalized medicine for patients around the world through universal access to molecular testing, by making molecular testing actionable, convenient, fast and suitable for any lab. The IdyllaTM platform is a fully automated sample-to-result, real-time PCR (Polymerase Chain Reaction) based system designed to offer in-house access to accurate molecular information in a minimum amount of time for faster, informed treatment decisions. IdyllaTM's continuously expanding menu of molecular diagnostic tests address key unmet clinical needs, with a focus in oncology. This is the fastest growing segment of the molecular diagnostics market worldwide. Today, Biocartis offers tests supporting melanoma, colorectal, lung and liver cancer, as well as for COVID-19, Flu, RSV and sepsis. For more information, visit www.biocartis.com or follow Biocartis on Twitter @Biocartis , Facebook or LinkedIn.

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. Please refer to the product labeling for applicable intended uses for each individual Biocartis product. 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. 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.

- 1 CDx = Companion diagnostics. A companion diagnostic (CDx) test is a test used as a companion to a therapeutic drug that helps predict if a patient is likely to respond to a treatment or not
- 2 A Lisbon (Portugal) based biotech company developing a precision medicine portfolio focused on liver cancer
- 3 AstraZeneca's third-generation EGFR-TKI (tyrosine kinase inhibitor) treatment