



PRESS RELEASE

REGULATED INFORMATION  
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## 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 CDx<sup>1</sup> 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 [Ophiomics](#)<sup>2</sup> 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 [June 2022](#), Biocartis launched its CE-marked, fully automated [Idylla™ GeneFusion Panel](#) (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 [June 2022](#), 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® (osimertinib<sup>3</sup>).
- In [September 2022](#), Biocartis announced the start of the commercialization in Europe of [SkylineDx's](#) innovative [Merlin Assay](#) 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 [September 2022](#), Biocartis announced its comprehensive recapitalization transaction aimed at securing adequate capital to support the Company's growth for the foreseeable future.

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

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 [Idylla™ EGFR Mutation Test](#) (CE-IVD) and the [Idylla™ GeneFusion Panel](#) (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.

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**More information:**

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**About Biocartis**

With its revolutionary and proprietary Idylla™ 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 Idylla™ 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. Idylla™'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](http://www.biocartis.com) or follow Biocartis on [Twitter @Biocartis\\_](#), [Facebook](#) or [LinkedIn](#).

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**Forward-looking statements**

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