



PRESS RELEASE

REGULATED INFORMATION

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Biocartis Meets 2019 Key Business Objectives

Mechelen, Belgium, 9 January 2020 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces to have met its latest 2019 key business objectives which were focused on three performance indicators: the installed base expansion of its Idylla™ molecular diagnostics platform, the growth of its Idylla™ cartridge volume and its year-end cash position.

Based on non-audited numbers, Biocartis today reports:

- *Installed base* – Biocartis realized 337 new instrument placements in 2019, within range of the latest guidance of 325-350 new instrument placements. Biocartis' installed base as per 31 December 2019 consequently grew to 1,310 Idylla™ instruments.
- *Cartridge volume* – In 2019, Biocartis realized a commercial volume of 175K cartridges, representing a year-over-year increase of 32%. The achieved growth is within range of the latest guidance of 30-35%.
- *Cash position* – As per 31 December 2019, Biocartis' cash position amounted to EUR 179m (non-audited number) versus the latest guidance of EUR 170-175m.

Additionally, Biocartis announced several operational achievements in 2019 that are expected to support further business growth, including amongst others:

- *Execution US go-to market strategy* – In September 2019, Biocartis announced a new go-to market strategy for the US market under which Biocartis' US direct sales team will drive commercialization going forward. Following the implementation of the new US go-to market strategy, the US direct sales team was strengthened and actions to address amongst others US market specific operational lessons learned in H1 2019 were implemented.
- *Execution Japan go-to market strategy* – Early 2019, Biocartis announced to have signed an agreement with Nichirei Biosciences¹ ('Nichirei Bio') for the product registrations and distribution of the Idylla™ platform in Japan. In October 2019, Nichirei Bio completed the registration of the Idylla™ Instrument and Idylla™ Console with the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan. With that, Nichirei Bio will now be able to offer the Idylla™ platform in combination with Idylla™ RUO² assays to local pathology laboratories in Japan, whilst both partners are further progressing in vitro diagnostic ('IVD') registration preparations for the Idylla™ assays.
- *Execution China go-to market strategy* – In Q1 2019, Biocartis announced the completion of the joint venture with Wondfo³, aimed at the commercialization of the Idylla™ platform in China with a first focus on the establishment of local manufacturing capabilities and product registrations.
- *Idylla™ test menu expansion* – Successful CE-marking of the Idylla™ MSI Test, which was announced on 28 February 2019 and which further strengthened Biocartis' colorectal cancer Idylla™ test menu, and launch of the liquid biopsy Idylla™ ctEGFR Mutation Assay (RUO³), which was announced on 25 October 2019.
- *New Idylla™ test menu partnerships* – In 2019, Biocartis announced two new partnerships with a focus on immuno-oncology. The first one is a collaboration agreement with Bristol-Myers Squibb Company that is focused on MSI testing in connection with immuno-oncology therapies and that allows for joint development and registrations of the Idylla™ MSI Test for use in a variety of indications, commercial settings and geographies. The second one is a master development and commercialization agreement with Kite Pharma⁴ which aims at the development of molecular-based assays on the Idylla™ platform that are supportive to Kite's therapies.
- *Idylla™ publications* – In 2019, the performance of Idylla™ was the subject of over 45 Idylla™ publications, of which several were selected for publication at large scientific conferences such as ESMO⁵ (European Society for Medical Oncology), ASCO⁶ (American Society of Clinical Oncology) and AMP⁷ (Association of Molecular Pathology).

1 Nichirei Biosciences Inc. is a leading supplier of biological and diagnostic products in Japan

2 Research Use Only, not for use in diagnostic procedures

3 Guangzhou Wondfo Biotech Co., Ltd. ('Wondfo', SHE: 300482) is a fast growing diagnostics leader in China

4 Kite Pharma, Inc., a Gilead Company

5 The European Society for Medical Oncology ('ESMO') congress took place between 27 September and 1 October 2019 in Barcelona (Spain)

6 The ASCO Annual Meeting of the American Society of Clinical Oncology took place between 30 May – 4 June 2019, Chicago (IL), US

7 AMP is the leading molecular diagnostics meeting that took place between 7-9 November 2019 in Baltimore, Maryland (US)

Herman Verrelst, Chief Executive Officer of Biocartis, commented: "After a rather turbulent Q3, we had a solid Q4, thanks to which we can today announce that we achieved our 2019 objectives in line with the latest guidance that we issued in September. The performance that we have seen in the US in Q4 is encouraging and indicates that the implementation of our new go-to market strategy is on track to further drive commercialization in that market. Our commercial strategies for Europe and Rest of World markets have continued to translate in good growth rates. Next to that, we are executing our commercialization plans for China and Japan. All these market penetration efforts in combination with anticipated further test menu expansion, including through menu partnerships, are expected to provide a solid basis for further growth in the coming years."

Biocartis will publish its 2019 full year results and 2020 guidance on 5 March 2020. On 16 January 2020, Biocartis' CEO Herman Verrelst will present at the [38th Annual J.P. Morgan Healthcare conference](#) in San Francisco (US) at 10:30 PST/19:30 CET.

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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 in oncology. This 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. Follow us on [Twitter](#): @Biocartis_.

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