PRESS RELEASE

REGULATED INFORMATION
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BIOCARTIS MEETS 2020 KEY OBJECTIVES

Mechelen, Belgium, 11 January 2021 - Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces to have met its 2020 key business objectives which were focused on three performance indicators: the installed base expansion of its rapid and easy-to-use 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 placed 335 new Idylla™ instruments in 2020, exceeding the latest guidance of 300 new instrument placements. Biocartis' installed base as per 31 December 2020 increased to 1,581 Idylla™ instruments[1].
- *Cartridge volume* – In 2020, Biocartis grew its commercial cartridge volume by 31%, slightly ahead of the latest guidance of 30%. In oncology, year-on-year growth both in Europe and in the US was largely offset by the distributor[2] markets, but strong demand for the Idylla™ SARS-CoV-2 Test[3] complemented overall volumes totaling 230k cartridges.
- *Cash position* – As per 31 December 2020, Biocartis' cash[4] position amounted to EUR 124m (non-audited number) versus the latest guidance of EUR 120m.

Herman Verrelst, Chief Executive Officer of Biocartis, commented: *"I am very pleased to announce that we achieved our initial 2020 outlook, despite the pandemic that severely disrupted and deprioritized cancer care globally. Patient access to hospitals was again significantly restricted in Q4 2020, causing test volumes to decrease across all regions. Nevertheless, we stayed on track and delivered on our pre-pandemic expectations thanks to the versatility of Idylla™ and its new pandemic test menu. The past year has clearly demonstrated the need for rapid response testing in an overburdened healthcare system, and we saw that we are very well equipped to deliver on our customers' needs in oncology as well as in infectious diseases. We made significant operational progress throughout 2020 on our path towards profitable growth. Therefore, we look ahead with confidence and start 2021 with a better than expected cash position that we plan to put at work to accelerate test menu expansion and diversification in a year that will again be marked by continued impact of the pandemic."*

In 2020, Biocartis made significant progress in laying the foundation for future profitable growth, with amongst others following achievements:

- *Expansion oncology partnerships* – In 2020, Biocartis launched several new partnerships to strengthen its oncology business:
  - In January 2020, Biocartis signed a master collaboration agreement with lung cancer targeted therapy leader AstraZeneca aimed at rapid and easy testing and expanded its partnership to, amongst others, the area of liquid biopsy testing using the Idylla™ ctEGFR Mutation Assay;
  - In March 2020, Biocartis expanded its partnership with Bristol-Myers Squibb Company (NYSE: BMY), to now also pursue, after the US, the registration of the Idylla™ MSI test as a companion diagnostic (CDx) test[5] in mCRC[6] in China;
  - In November 2020, Biocartis announced its entry in the thyroid cancer domain with the signing of a license, development and commercialization agreement with GeneproDx[7] for the development of GeneproDx' novel genomic test ThyroidPrint® on the Idylla™ platform.
- *Expansion infectious disease partnerships* – Following amongst others the market shift due to the pandemic, in 2020, Biocartis launched several new partnerships to gradually expand its infectious disease test menu:
  - In March 2020, the agreement with Immunexpress[8] was expanded with a co-commercialization agreement for the SeptiCyte® RAPID test for use on the Idylla™ platform;
  - In September 2020, the agreement with LifeArc[9] was expanded to now also develop highly innovative prototype assays in the field of infectious and immune related diseases on the Idylla™ platform;

1 Excluding instruments returned by Exact Sciences in accordance with the termination agreement announced on 29 October 2020
2 Defined as the world excluding European direct markets, US, China and Japan
3 In the US, distribution of the Idylla™ SARS-CoV-2 Test was initiated in Q3 2020 per US FDA Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised), May 2020, Section IV.C. Commercial Manufacturer Development and Distribution of Diagnostic Tests Prior to EUA Submission
4 Consisting of cash and cash equivalents
5 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
6 Metastatic colorectal cancer
7 A molecular diagnostics company based in Santiago, Chile
8 A Seattle-based (WA, US) molecular diagnostic company
9 LifeArc, formerly known as the Medical Research Council Technology (MRC Technology, MRCT) is a London (UK) based life science medical research charity

- In October 2020, the partnership with Bristol-Myers Squibb Company (NYSE: BMY) was expanded into the infectious disease domain with the announcement of Biocartis joining the COVID-19 Testing Industry Consortium, aimed at improving, innovating and accelerating all aspects of COVID-19 testing[10];
- In November 2020, a new partnership was signed with Endpoint Health[11] aimed at the development and commercialization of a novel CDx[5] test on Idylla™ for critical illnesses.

- *Idylla™ test menu expansion* – Biocartis made further progress in its Idylla™ oncology test menu, with the development of its highly innovative Idylla™ GeneFusion Assay, expected to be launched as a RUO[12] in Q1 2021, for which it announced to have received a EUR 1.2 million grant from VLAIO[13] in September 2020. In the field of infectious disease, Biocartis announced in September 2020 the market release of the SeptiCyte© RAPID test on Idylla™ (CE-IVD)[14], followed by the CE-IVD launch of its Idylla™ SARS-CoV-2 Test[3] in November 2020.
- *Idylla™ publications* – In 2020, several studies and abstracts once again demonstrated the excellent performance of Idylla™:
  - In September 2020, the FACILITATE[15] study[16], launched as part of the agreement between Biocartis and AstraZeneca (LON: AZN), was selected for presentation at the renowned European Society for Medical Oncology ('ESMO') Virtual Congress[17];
  - In November 2020, at the annual meeting of the 'Association for Molecular Pathology[18]' (AMP), ten Idylla™ studies were published which highlighted the strengths of the Idylla™ platform and assays[19] in terms of performance, ease of use and turnaround time, as well as Idylla™'s capacity to overcome the obstacles of working with small amounts of sample[20];
  - Also in November 2020, a global multi-centre real world study[21] with the Idylla™ MSI Assay was published and demonstrated excellent performance of the Idylla™ MSI Assay (RUO)[12] with a very low failure rate. The study was the largest so far published for Biocartis.

Biocartis will publish its 2020 full year results and 2021 guidance on 25 February 2021.

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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 and sepsis. More information: www.biocartis.com. Follow us on Twitter: @Biocartis_.

10 Including research, regulatory oversight, clinical implications, reliability and access
11 A Palo Alto, CA (USA) based company developing personalized care solutions and targeted therapies for critically ill patients
12 RUO = Research Use Only, not for use in diagnostic procedures
13 The Flanders organization for Innovation & Entrepreneurship. The Idylla™ GeneFusion Assay will include a highly multiplexed panel of established and emerging biomarkers, and will be the first FFPE (formalin fixed, paraffin embedded) RNA based assay on the Idylla™ platform
14 Developed in collaboration with Immunexpress
15 Hummel M. et al, "*FACILITATE: a real-world multicentre prospective study investigating the utility of a rapid, fully automated RT-PCR assay vs reference methods (RM) for detecting epidermal growth factor receptor mutations (EGFRm) in NSCLC*", ESMO Virtual Congress 2020 (19-21 September 2020), first published online on 14 September 2020
16 A large, prospective, study across 16 European sites in Belgium, France, Germany and Italy. The study aimed to prospectively test 100 paraffin-embedded biopsy or cytology tissue samples with ≥10% neoplastic cells per site, from patients with advanced NSCLC (non-small cell lung cancer)
17 That took place between 19-21 September 2020
18 A leading molecular diagnostics conference that took place virtually this year between 16-20 November 2020
19 All studies were performed with Idylla™ RUO assays, research use only, not for use in diagnostic procedures. Three studies also discussed new Biocartis assays in the area of infectious disease: the Idylla™ SARS-CoV-2 Assay and the SeptiCyte® RAPID on Idylla™
20 This represents a major challenge for many current molecular testing methods in a variety of different cancer types
21 A. Velasco et al., Multi-center real-world comparison of the fully automated Idylla™ microsatellite instability assay with routine molecular methods and immunohistochemistry on formalin-fixed paraffin-embedded tissue of colorectal cancer, Virchows Archiv, https://doi.org/10.1007/s00428-020-02962-x, November 2020

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