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BIOCARTIS Q1 2020 BUSINESS UPDATE

Mechelen, Belgium, 23 April 2020 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today provides a business update for the first quarter of 2020 and an updated outlook for the full year 2020.

Key messages

- **Commercial cartridge volume:** Year-on-year Q1 growth of 68% in commercial cartridge volume demonstrating the growth potential within a well-established customer base across all regions. Europe remains the largest contributor led by very strong performance in Northern, Central and Western European markets, partially fueled by pro-active stock orders in light of the COVID-19 pandemic.
- **Installed base:** Slower than expected installed base expansion across markets in Q1 2020 due to the global COVID-19 pandemic, with main impact suffered in Southern European, the US and RoW[1] markets.
- **Partnerships:** Successful partnership expansions in oncology with AstraZeneca, with a study on liquid biopsy testing using the Idylla™ ctEGFR Mutation Assay (RUO[2]), and with Bristol Myers Squibb Company (BMS), with a new project aimed at pursuing the registration of the Idylla™ MSI test as a companion diagnostic[3] (CDx) test in metastatic colorectal cancer (mCRC) in China, as well as a successful expansion of the partnership in infectious diseases with Immunexpress Pty Ltd ('Immunexpress') for the co-commercialization in Europe of the SeptiCyte® RAPID Test on Idylla™, which recently received CE-marking.
- **Menu of tests:** Development of the Idylla™ SARS-CoV-2 test, the virus that causes COVID-19, for rapid and easy testing of individuals with flu-like symptoms. When used in combination with recently CE-marked IVD SeptiCyte® RAPID Test[4] on Idylla™, this testing solution has the unique potential to identify patients with severe disease, as recent data[5] indicate that sepsis is the most frequently observed complication in COVID-19[6].
- **Appointment new CFO**: Biocartis announces the appointment of Jean-Marc Roelandt as the new Chief Financial Officer ('CFO') of the Company with immediate effect. Jean-Marc Roelandt is a Senior executive with an established track record of more than 25 years as CFO in globally active publicly listed companies. Prior to joining Biocartis, he was CFO of MDxHealth.
- **Cash position:** Biocartis' cash position end Q1 2020 amounted to EUR 170.1m (unaudited figure).

COVID-19 impact on full year 2020 guidance

Due to the COVID-19 pandemic, new Idylla™ instrument placements slowed down towards end Q1 2020 as access to hospitals was restricted. As there is limited visibility on when these restrictions will be lifted and as Idylla™ instrument sales may temporarily further suffer from budgetary restrictions across all healthcare systems in the aftermath of the global pandemic, the Company is suspending its guidance on instrument placements in 2020 and will provide an update as soon as normal business activity resumes. Furthermore, Biocartis expects that this temporary slowdown may in turn moderate the growth of cartridge volumes during the second half of the year, although the expanded collaboration in infectious diseases with Immunexpress and the planned launch of a SARS-CoV-2 test on the Idylla™ platform could offset this impact. With this shift in product mix, Biocartis sees potential to still meet its 2020 commercial cartridge volume objective, however given current uncertainties around timing of normalization, the Company currently also suspends guidance on commercial cartridge volume growth. The cash position is still targeted to be in the range of EUR 110m by year-end 2020.

Commenting on the Q1 2020 Business Update, Herman Verrelst, Chief Executive Officer of Biocartis, reacted: *"We were off to a good start in Q1 2020 with an outperformance in commercial cartridge growth in our US and European markets, especially in North, Central and Western Europe, and a good continued growth in our RoW markets, before the COVID-19 pandemic disturbed commercial markets across the globe as from March 2020. Despite the global pandemic, existing customers were able to continue to order. We even saw an increase towards the end of Q1 at some of our larger customers in Northern Europe, of which some increasingly switched their oncology testing to our easy and fully automated Idylla™ technology, in times where lab workers and resources*

1 RoW = Rest of the World. RoW is defined as the world excluding European direct markets, US, China and Japan
2 RUO = Research Use Only, not for use in diagnostic procedures
3 An IVD companion diagnostic device is an in vitro diagnostic device that provides information that is essential for the safe and effective use of a corresponding therapeutic product. Source: US FDA, last consulted on 7 April 2020
4 Developed in collaboration with Immunexpress. More info here.
5 Zhou et al., Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study, published online 9 March 2020, https://doi.org/10.1016/S0140-6736(20)30566-3
6 Sepsis developed at a median of 9 days (7–13) after illness onset among all patients, followed by ARDS (12 days [8–15]), acute cardiac injury (15 days [10–17]), acute kidney injury (15 days [13–19.5]), and secondary infection (17 days [13–9])

are being prioritized on COVID-19 testing. The global pandemic however considerably affects our installed base growth, as our commercial teams had to cease all hospital and lab prospective visits. Furthermore, we expect that in Q2 and likely as well in H2 2020 we will see a slow-down in commercial cartridge volume growth from the 68% we achieved in Q1 2020. The strength of our Idylla™ platform however brings us resilience in these difficult times, which is demonstrated by the newly announced development of an Idylla™ SARS-CoV-2 test that can make a true difference on every installed Idylla™ instrument worldwide, for rapid and easy testing of individuals with flu-like symptoms, and even as a support for oncology patients as COVID-19 test, before hospital surgeries take place. Furthermore, we expanded our partnership with Immunexpress, who recently launched the CE-marked IVD SeptiCyte® RAPID Test on Idylla™, and for which we will act as exclusive distributor in Europe. Together with the SeptiCyte® RAPID Test, this combined testing solution on Idylla™ also has the unique potential to more efficiently triage patients with flu-like symptoms, which could potentially prevent unnecessary ICU admissions or reduce average length of hospital stays. We are pleased to see that, together with our partners, we have the flexibility with our Idylla™ platform to respond to highly unmet needs in society, whether it is in oncology or infectious diseases, and to safeguard the long-term value of the company. Although this is undeniably a difficult time for everyone, we remain confident of the value we can bring to our customers, patients and society."

Commercial highlights

- *US commercialization* – Continued expansion in installed base in US markets was demonstrated at the start of Q1 2020, underlining the success of the direct US sales strategy where positive customer feedback resulted in the attraction of new reference Idylla™ users that presented several Idylla™ posters and abstracts at the global USCAP conference in March 2020 (see below). During Q1 2020, the US represented over 40% of new Idylla™ instrument placements, however growth of both installed base expansion and commercial cartridge volume stalled due to the COVID-19 impact, as access to hospitals and labs was restricted.
- *European commercialization* – European direct markets realized robust cartridge volume growth during Q1 2020 predominantly driven by outperformance in Northern, Central and Western European markets.
- *RoW commercialization* – Commercial cartridge volume growth in RoW distribution markets continued in Q1 2020 driven by increased use of Idylla™ on the existing RoW installed base of which the expansion however was impacted due to the COVID-19 disturbance in commercial activities of RoW distribution partners. During Q1 2020, new market authorizations were also obtained for the Idylla™ MSI Test in Colombia and Canada and for the Idylla™ EGFR Mutation Test in Argentina.

Menu and partnership highlights

- *Idylla™ SARS-CoV-2 test* – On 23 April 2020, Biocartis announced the development of a SARS-CoV-2 test, the virus that causes COVID-19, on Idylla™. The test will be based on the Idylla™ Respiratory (IFV-RSV) Panel[7] that received 510(k) clearance by the US FDA on 5 September 2017 and is being designed to detect SARS-CoV-2 from respiratory samples such as nasopharyngeal swabs. Upon regulatory approval, the Idylla™ SARS-CoV-2 test is targeted to help healthcare providers manage the COVID-19 pandemic through rapid and easy testing of individuals with flu-like symptoms. In addition, the Idylla™ SARS-CoV-2 test may be used in combination with the recently CE-marked IVD SeptiCyte® RAPID Test[8] on Idylla™ to facilitate management of patients within the hospital intensive care unit (ICU). When used together, this combined testing solution on Idylla™ has the unique potential to identify patients with severe disease, as recent data[9] indicate that sepsis is the most frequently observed complication in COVID-19[10]. Biocartis develops the Idylla™ SARS-CoV-2 test with support from multiple undisclosed partners as part of a joint commitment to respond to the COVID-19 pandemic. Subject to a successful 'Emergency Use Authorization' by the US FDA, launch of the Idylla™ SARS-CoV-2 test is expected in H2 2020[11]. The US FDA 510(k) clearance of the SeptiCyte® RAPID Test on Idylla™ is expected along the same timelines.
- *Partnership AstraZeneca* – On 22 January 2020, Biocartis announced that it entered into a master collaboration agreement with AstraZeneca, a global science-led biopharmaceutical company (LON/STO/NYSE: AZN). The scope of the new master collaboration agreement enables collaborative development and commercialization projects between Biocartis and AstraZeneca, such as but not limited to, CDx development projects that may cover any type of indication or biomarker. The first project in that context is a study focused on evaluating if liquid biopsy testing using the Idylla™ ctEGFR Mutation Assay (RUO) could provide further benefits to tissue-based EGFR molecular testing.

7 Legally acquired in 2018 from Janssen Diagnostics, a division of Janssen Pharmaceutica NV ('Janssen') who co-developed the assay Source: https://investors.biocartis.com/sites/default/files/press-releases/2019/170904-PR-510k-clearance-IFV-RSV-Panel-ENG.pdf
8 Developed in collaboration with Immunexpress. More info here.
9 Zhou et al., Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study, published online 9 March 2020, https://doi.org/10.1016/S0140-6736(20)30566-3
10 Sepsis developed at a median of 9 days (7–13) after illness onset among all patients, followed by ARDS (12 days [8–15]), acute cardiac injury (15 days [10–17]), acute kidney injury (15 days [13–19.5]), and secondary infection (17 days [13–9])
11 Subject to interactions with the US FDA. Immunexpress expects US FDA 510(k) clearance of the Septicyte® RAPID Test on Idylla™ around the same timeline in H2 2020

- *New BMS Immuno-Oncology MSI Project in China* – On 5 March 2020, Biocartis announced a new project under its existing collaboration with Bristol-Myers Squibb Company (NYSE: BMY), a global biopharmaceutical company. The existing collaboration aims at the potential registration and use as a CDx of the Idylla™ MSI test in connection with immuno-oncology therapies of Bristol-Myers Squibb. The initial focus under the collaboration is to achieve registration in the United States of the Idylla™ MSI test as a CDx test in metastatic colorectal cancer (mCRC). Bristol-Myers Squibb and Biocartis have now agreed to add a new project under their collaboration which pursues the registration of the Idylla™ MSI test as a CDx test in mCRC[12] in the People's Republic of China.
- *Expansion Immunexpress partnership* – On 26 March 2020, Biocartis announced the co-commercialization agreement with Immunexpress of the newly CE-marked IVD SeptiCyte® RAPID Test on Idylla™, in which Biocartis will lead commercialization in Europe as exclusive distributor of the SeptiCyte® RAPID Test, while Immunexpress will lead commercialization in the US. The SeptiCyte® RAPID Test is a rapid, host-response[13] test that distinguishes sepsis from non-infectious SIRS (systemic inflammatory response syndrome) and is expected to provide actionable results in about one hour[14]. Recent data[15] indicate that sepsis is the most frequently observed complication in COVID-19[16].
- *European performance studies* – During Q1 2020, seven[17] new Idylla™ performance publications[18] were issued in Europe. All Idylla™ studies demonstrated excellent performance of Idylla™ compared to other methods, in combination with the ease of use and fast turnaround time of the Idylla™ platform. The studies included, amongst others, a feasibility study[19] on the Idylla™ NRAS-BRAF Mutation Test[20] to research the direct use of thyroid FNA (Fine Needle Aspirate) samples as a Rapid On site Molecular Evaluation (ROME) solution for the rapid and easy detection of NRAS and BRAF mutations without having to send out the samples to specialized, centralized labs.
- *USCAP abstracts & posters* – During the global annual pathology conference USCAP, that took place in Los Angeles, CA (US) between 2 - 4 March 2020, four Idylla™ abstracts and posters[21] were published by key oncology opinion leaders, including amongst others Dartmouth-Hitchcock Medical Center (Lebanon, New Hampshire, US), Vitro Molecular Laboratories (Miami, Florida, US), the University of New Mexico (Albuquerque, New Mexico, US) and the William Osler Health System (Brampton, Ontario, Canada). The respective Idylla™ abstracts and posters showed strong data of Idylla™ assays (RUO) including several studies that used the Idylla™ EGFR Mutation Assay (RUO), which demonstrated reliable and rapid EGFR testing to be used to complement conventional NGS testing.

Operational and financial highlights

- *Appointment new CFO* – On 27 January 2020, Biocartis announced that Ewoud Welten, the Company's CFO, has decided to resign from Biocartis and to pursue an opportunity in the Netherlands, closer to his home and family. The Company now appoints Jean-Marc Roelandt as the new CFO of the Company with immediate effect. Jean-Marc Roelandt is a Senior executive with an established track record of more than 25 years as CFO in globally active publicly listed companies. With a focus on M&A, capital market transactions and the implementation of adequate financial management infrastructure in dynamic and fast growing companies, he built up a solid expertise in various industries. Prior to joining Biocartis, he was CFO of MDxHealth, a healthcare company that provides actionable genomic information to personalize the diagnosis and treatment of cancer.
- *COVID-19 business continuity* – To ensure business continuity during the COVID-19 pandemic, measures were implemented to ensure safe working conditions for all employees as well as to ensure continued commercial production of Idylla™ cartridges on the two manufacturing lines in Mechelen (Belgium) during Q1 2020.
- *Cash position* - Biocartis' cash position end Q1 2020 amounted to EUR 170.1m (unaudited figure).

12 mCRC = Metastatic colorectal cancer
13 Host-response based tests focus on measuring biomarkers that are indicative of the response of a patient's immune system to an infection rather that measuring pathogens that are the cause of the infection
14 Moreover, SeptiCyte® RAPID not only discriminates sepsis from SIRS but also correlates with viral sepsis infection, versus procalcitonin (PCT) which increases with severity of bacterial but not viral infection and is also a non-specific marker of inflammation
15 Zhou et al., Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study, published online 9 March 2020, https://doi.org/10.1016/S0140-6736(20)30566-3
16 Sepsis developed at a median of 9 days (7–13) after illness onset among all patients, followed by ARDS (12 days [8–15]), acute cardiac injury (15 days [10–17]), acute kidney injury (15 days [13–19.5]), and secondary infection (17 days [13–9])
17 Of which two studies were published in epub, ahead of print in Q2 2020
18 De Luca C et al., '*Rapid On-site Molecular Evaluation in thyroid cytopathology: A same-day cytological and molecular diagnosis'.* Diagn Cytopathol. Diagn Cytopathol. 2020 Apr;48(4):300-30. Epub 6 Jan 2020; Zwaenepoel K et al., '*Clinical Performance of the Idylla™ MSI Test for a Rapid Assessment of the DNA Microsatellite Status in Human Colorectal Cancer'.* J Mol Diagn. March 2020; 22 (3): 386-395.. Epub 24 Dec 2019; Chevalier L et al., '*EGFR molecular characterization in non-small cell bronchic cancer: comparative prospective study by NGS and Idylla™ platform technologies'.* Annales de Pathologie. Feb 2020; Merlin MS et al., '*Rapid fully-automated assay for routine molecular diagnosis of BRAF mutations for personalized therapy of low grade gliomas'.* Pediatr Hematol Oncol. 2020 Feb;37(1):29-40. Epub 23 Oct 2019; Franczak C et al., '*Evaluation of KRAS, NRAS and BRAF mutations detection in plasma using an automated system for patients with metastatic colorectal cancer'.* PLoS One. 15 Jan 2020 ;15(1); Bocciarelli C. et al., '*Evaluation of the Idylla™ system to detect the EGFRT790M mutation using extracted DNA'.* Pathol Res Pract. 2020 Jan;216(1). Epub 2 Dec 2019; Boureille A et al. 'Rapid detection of EGFR mutations in decalcified lung cancer bone metastasis', Bone Oncol. January 2020 (Epub ahead of print)
19 De Luca C et al., 'Rapid On-site Molecular Evaluation in thyroid cytopathology: A same-day cytological and molecular diagnosis'. Diagn Cytopathol. Diagn Cytopathol. 2020 Apr;48(4):300-30. Epub 6 Jan 2020
20 The Idylla™ NRAS-BRAF Mutation Test is intended for use on FFPE samples (Formalin Fixed, Paraffin Embedded) and not for use on FNA samples. Please refer to the Biocartis product labeling for intended use of the assay
21 R. Gadde et al., '*Validation of the Idylla™ EGFR Assay for Rapid Assessment of EGFR Mutation Status in Non-small Cell Lung Cancer',* Dartmouth Hitchcock Medical Center, Lebanon, NH; H Yaziji et al., '*Validation of a Rapid PCR Assay for Microsatellite Instability Testing in Colorectal Cancer',* Vitro Molecular Laboratories, Miami, FL; J Gralewski et al., '*Detection of EGFR Exons 18-21 Hotspot Mutations Using a Fully-Automated, Cartridge-Based Platform with Ultra-Rapid Turnaround Time: A Comparison Study with Conventional Next Generation Sequencing',* University of New Mexico, Albuquerque, NM; P. Matthews et al., '*Clinical Impact of Rapid Biomarker Testing in Non-Small Cell Lung Cancer in a Community Setting',* William Osler Health System, Brampton, ON, Canada

Outlook

- *COVID-19 impact on full year 2020 guidance*: see above.
- *Test menu outlook:*
  - Colorectal cancer menu – Subject to further feedback from US FDA interaction, US FDA 510(k) submission of the Idylla™ MSI Test is expected by end 2020 and the timing of the US FDA submission of PMA (Pre-Market Approval) application for the Idylla™ RAS tests is being assessed;
  - Lung cancer menu – Further development of the Idylla™ GeneFusion Assay towards expected RUO launch by end 2020;
  - Breast cancer menu – Start of the clinical validation studies of the Idylla™ IVD Oncotype DX Breast Recurrence Score® test in France and Germany is expected in 2020;
  - Infectious disease partner menu – US FDA 510(k) clearance for the SeptiCyte® RAPID Test on Idylla™ is expected by Q3 2020 and US FDA Emergency Use Authorization for the Idylla™ SARS CoV-2 test is expected in H2 2020.
- *Cash position*: Targeted cash position in the range of EUR 110m by 2020 year-end.

Financial calendar 2020

- 8 May 2020 Annual and Extraordinary Shareholders' Meetings Biocartis Group NV
- 3 September 2020 H1 2020 results
- 12 November 2020 Q3 2020 Business Update

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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. 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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