PRESS RELEASE

REGULATED INFORMATION
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BIOCARTIS Q1 2021 BUSINESS UPDATE

70% Cartridge Volume Growth in Q1 2021;
New Partnership with SkylineDx on Melanoma Testing

Mechelen, Belgium, 22 April 2021 – 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 2021 and the outlook for the full year 2021.

Commenting on the Q1 2021 Business Update, Herman Verrelst, Chief Executive Officer of Biocartis, said: *"Building on investments made last year, we started the year off strong with 70% year-over-year growth of our commercial cartridge volume in Q1 2021. Similar to 2020, growing volumes in oncology were supplemented by continued demand for our Idylla™ SARS-CoV-2 Test[1]. Oncology volumes were ahead of expectations in European and distributor markets[2] while the US cartridge volume growth was still strongly driven by our Idylla™ SARS-CoV-2 Test. We made good progress on menu expansion, both in oncology as well as in infectious diseases, and we remain poised for strong growth in 2021. End of March, we launched the highly innovative Idylla™ GeneFusion Assay (RUO[3]), which makes fully automated gene fusion testing possible as from now on, even for smaller labs. We also continued to work on our regulatory program: just a few days ago, we achieved a major milestone with our very first US FDA oncology assay submission to the US FDA, with the 510(k) submission of our Idylla™ MSI Test. Once obtained, both large and small US labs will be able to benefit from our fast and easy to use Idylla™ MSI testing. Finally, we strengthened existing pharma collaborations and welcomed a new content partner, SkylineDx, Our first project with SkylineDx will focus on the development of an Idylla™ version of their Merlin Assay to help predict a patient's risk of nodal metastasis in melanoma, which matches well with our existing Idylla™ BRAF Mutation Test (CE-IVD)[4] for metastatic melanoma therapy guidance. Despite lingering uncertainties due to the pandemic, we continue to make progress on all fronts. We are well on track with our menu expansion plans, which will fuel further volume and revenue growth."*

Q1 2021 HIGHLIGHTS

- **Commercial cartridge volume:**
  - Year-over-year growth of 70%
  - Better than expected performance in Europe, both in oncology and in infectious diseases
  - Strong growth in the US, driven by continued demand for the Idylla™ SARS-CoV-2 Test
  - Oncology volumes in distributor markets back on track and growing beyond expectations
- **Idylla™ installed base:**
  - Continued expansion of Idylla™ installed base in line with expectations, led by European markets
  - US laboratory operations not yet normalized, causing a slower than expected start of 2021
- **Idylla™ test menu:**
  - Encouraging reception and initial demand for the new Idylla™ GeneFusion Assay (RUO) which was launched end of March 2021
  - First oncology assay US FDA submission with the 510(k) notification for the Idylla™ MSI Test to aid in the differentiation between sporadic colorectal cancer (CRC) and potential Lynch syndrome
- **Partnerships:**
  - New partnership with SkylineDx for the development of SkylineDx' novel proprietary Merlin Assay on Idylla™, aimed at predicting a patient's risk of nodal metastasis in melanoma
  - Partnership with Amgen reoriented towards the evaluation of the suitability of Biocartis technology as a potential companion diagnostic[5] for an undisclosed research program. Due to the market need and opportunities in this area, both parties decided to discontinue their ongoing project in the colorectal cancer area aimed at PMA submission of the Idylla™ RAS tests with the US FDA and to resource the new high-priority feasibility assessment program
- **Financial:**
  - End of Q1 2021, Biocartis' cash position amounted to EUR 108.1m (unaudited figure).

Commercial highlights

- *Commercial cartridge volume* – Strong start of the year in Q1 2021 with overall commercial cartridge volumes that grew 70% year-over-year. This was mainly driven by a higher than expected performance across European and distributor markets in oncology, supplemented by continued demand for the Idylla™ SARS-CoV-2 Test. In the US, after a strong finish of 2020, ordering volumes in oncology[6] were pushed out towards

1 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. The Idylla™ SARS-CoV-2 Test was CE-marked on 10 November 2020 and in August 2020, Biocartis submitted a notification of intent to distribute and request for 'Emergency Use Authorization' (EUA) from the US FDA for the Idylla™ SARS-CoV-2 Test
2 Defined as the world excluding European direct markets, US, China and Japan
3 RUO = Research Use Only, not for use in diagnostic procedures
4 The Idylla™ BRAF Mutation Test, performed on the Idylla™ platform, is an in vitro diagnostic Test for the qualitative detection of V600E/E2/D and V600K/R/M mutations in codon 600 of the BRAF gene. The Idylla™ BRAF Mutation Test, from sample-to-result, starts with formalin-fixed paraffin-embedded (FFPE) human tissue from metastatic melanoma to liberate DNA for subsequent real-time PCR amplification and detection
5 A 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 All Idylla™ assays sold in the US are for Research Use Only

the end of Q1 2021, but demand for the Idylla™ SARS-CoV-2 Test remained at attractive levels. While Idylla™ SARS-CoV-2 testing volumes fueled growth in Q1 2021, vaccination campaigns start to impact testing volumes, especially in the US where supply and demand start balancing out.

- *Installed base* – Overall, placements of new instruments tracked the expectations, in part driven by Idylla™ SARS-CoV-2 testing needs.
- *Regulatory update distributor markets* – During Q1 2021, the Idylla™ platform, the Idylla™ BRAF Mutation Test (CE-IVD) and the Idylla™ EGFR Mutation Test (CE-IVD) completed registration in Russia, and the Idylla™ MSI Test completed registration in Taiwan, as such expanding the distribution network for Biocartis' IVD medical devices.

Test menu and partnership highlights

During Q1 2021, Biocartis took important steps in the build-out of its oncology business.

- *Idylla™ GeneFusion Assay* – On 22 March 2021, Biocartis announced the long-awaited launch of its highly innovative Idylla™ GeneFusion Assay (RUO). The Assay detects, in one single cartridge, a wide range of biomarkers covering all gene fusions considered to be relevant in cancer research. The Idylla™ GeneFusion Assay (RUO) is therefore expected to provide a much faster testing solution for laboratories, compared to other testing methods including Next-Generation Sequencing (NGS) testing which often takes days or even weeks before results are available.
- *US FDA submission Idylla™ MSI Test* – On 20 April 2021, Biocartis announced its first oncology assay US FDA submission with the 510(k) submission[7] of the Idylla™ MSI Test[8] for use as an *in vitro* diagnostic device intended for the identification of microsatellite instability (MSI) status in colorectal (colon) cancer (CRC) to aid in the differentiation between sporadic CRC and potential Lynch syndrome.
- *Partnership Amgen* – After the reporting period, Biocartis and Amgen, a leading biotechnology company (NASDAQ: AMGN), agreed on initiating a feasibility assessment aimed at evaluating the suitability of Biocartis technology as a potential companion diagnostic for an undisclosed research program. Due to the market need and opportunities in this area, both parties decided to discontinue their ongoing project in the colorectal cancer area aimed at PMA submission of the Idylla™ RAS tests with the US FDA, and to resource the new high-priority feasibility assessment program.
- *Partnership SkylineDx* – After the reporting period, on 22 April 2021, Biocartis announced the signing of partnership agreement with SkylineDx, which targets the development of SkylineDx' novel proprietary test, the Merlin Assay, on the Idylla™ platform and is aimed at predicting a patient's risk of nodal metastasis in melanoma. Under the terms of the agreement, SkylineDx will lead the development of the Merlin Assay on Idylla™, while Biocartis will lead commercialization in Europe through its growing Idylla™ network. As part of the agreement and based on SkylineDx' highly valuable portfolio of novel molecular tests in varying stages of development and expected attractive value-based pricing, Biocartis will invest up to EUR 10m in secured convertible notes to be issued by SkylineDx in different project-based instalments throughout the collaboration.

Organizational and operational highlights

- *Cartridge manufacturing* – During Q1 2021, the transfer of the Idylla™ EGFR Mutation Test (CE-IVD) to the second cartridge manufacturing line ('ML2') was completed. This concluded the transfer of Biocartis' main oncology assays on ML2, which is a key driver of cost optimizations within the Company's cartridge manufacturing activities.

Financial highlights

- *Cash position* – End of Q1 2021, Biocartis' cash position amounted to EUR 108.1m (unaudited figure).
- *Revised credit facility* – During Q1 2021, Biocartis entered into a new credit facility with KBC Bank, replacing the facilities with KBC Bank and BNP Paribas Fortis that came to maturity in 2020. This facility consists of a EUR 7.5m straight loan and a EUR 7.5m rollover credit line. To date, the new credit facility remains undrawn.

Outlook

During Q1 2021, vaccination campaigns were initiated and the need for basic COVID-19 testing will most likely gradually reduce. Further normalization should favor oncology instrument installed base and cartridge growth, especially in the US. After summer, more typical seasonal viruses such as influenza and RSV may start spreading again as vaccination progresses and contact restrictions loosen. To address potential new testing needs and alleviate potential pressure on oncology testing volumes, Biocartis continues the development of the Idylla™ SARS-CoV-2/Flu/RSV Panel. Despite these continued uncertainties around the global development of the pandemic and its impact on molecular diagnostic testing both in oncology and in infectious diseases, Biocartis reconfirms its 2021 guidance:

- *Commercial cartridge volume:* Targeting a year-over-year growth of 40%-60% or commercial cartridge volumes in the range of 320k-370k. The high-end of the range will only be delivered in case of consistent

7 A 510(k) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). A 510(k) or Premarket Notification (PMN) with the US FDA is required when introducing a device into commercial distribution for the first time. Source: https://www.fda.gov/medical-devices/products-and-medical-procedures/device-approvals-denials-and-clearances, last consulted on 24 March 2021

8 The Idylla™ MSI Test, for use on the Idylla™ system, is intended for the qualitative identification of microsatellite instability (MSI) in colorectal cancer (CRC) tumors and to aid in the differentiation between sporadic CRC and potential Lynch Syndrome. The clinical performance of this device to guide treatment of MSI-H patients has not been established. The Idylla™ MSI Test uses formalin-fixed, paraffin-embedded (FFPE) tissue sections of human CRC tumor, from which nucleic acids are liberated, then analyzed using PCR amplification of seven monomorphic biomarkers and subsequent melt-curve analysis

strong demand for the Idylla™ SARS-CoV-2 Test or its successor the Idylla™ SARS-CoV-2 Panel at attractive average selling prices throughout 2021;
- *Installed base:* Targeting 300-350 new Idylla™ instrument placements;
- *Cash position:* Targeting at least EUR 50m cash position at year-end, including potential investments in upgrading and expanding the infectious diseases menu.

Financial calendar 2021
- 14 May 2021 Annual and Extraordinary Shareholders' Meetings Biocartis Group NV
- 2 September 2021 H1 2021 results
- 10 November 2021 Q3 2021 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, 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_.