BIOCARTIS Q3 2020 BUSINESS UPDATE

Mechelen, Belgium, 12 November 2020 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today provides a business update for the third quarter of 2020 and the outlook for the full year 2020.

Commenting on the Q3 2020 Business Update, Herman Verrelst, Chief Executive Officer of Biocartis, said: *"During Q3 2020, overall growth of cartridge volumes further recovered from the significant impact of the pandemic in Q2 2020. In the US, cartridge volumes in oncology were back at pre-pandemic levels and we picked up with growth again. Also in the US, we saw that our Idylla™ SARS-CoV-2 Test[1] is strengthening our footprint within our core customer base that is in need of a platform that delivers rapid response testing, both in oncology and in infectious diseases. With the recent CE-IVD marking of the Idylla™ SARS-CoV-2 Test we can now do the same for our European customers. Barring any pandemic-related deterioration of business conditions towards the end of the year, we are confident that we can deliver on our growth targets for the year. We had a setback with the termination of our collaboration with Genomic Health, but our partner strategy remains strong with two new partnerships initiated. The collaboration with GeneproDx marks our entry in the thyroid cancer domain with ThyroidPrint®, a proven test[2] aimed to help determine whether a thyroid nodule with an indeterminate cytology result is benign or malignant, and as such may contribute to reducing unnecessary surgery. The new partnership with Endpoint Health and the successful market releases in Europe of the Idylla™ SARS-CoV-2 Test and SeptiCyte® RAPID[3] on Idylla™ again demonstrate the versatility of the Idylla™ platform as one single, fully automated solution for both oncology and infectious diseases testing, which is expected to drive further growth in Q4 2020 and beyond."*

Commercial highlights

- *Commercial cartridge volume* – During Q3 2020, overall commercial cartridge volumes recovered from the significant impact of the pandemic in Q2 2020 and grew 61% year-on-year. With year-to-date growth in commercial cartridge volume in Q3 2020 standing at 27%, Biocartis is on track to achieve the targeted 30% growth for FY2020. The US returned to the growth of commercial cartridge volumes in oncology, complemented by initial sales of the Idylla™ SARS-CoV-2 Test[1]. European markets showed consistent growth within oncology, fully in line with pre-pandemic expectations. In Rest of World (RoW[4]) markets, the year-on-year growth during Q3 2020 was moderate, while year-to-date growth is still stalling due to the continued impact of the pandemic.
- *Installed base* – During Q3 2020, the Idylla™ installed base continued to expand, with the US representing 50% of all new Idylla™ placements. The lingering impact of the pandemic continued to slow down the Idylla™ instrument growth in RoW markets.
- *Regulatory update RoW markets* – End of October 2020, the Taiwan FDA (TFDA) has accepted registrations for the Idylla™ platform and the Idylla™ EGFR Mutation Test (CE-IVD).

Test menu highlights

- *Oncology* – Advancements in the lung cancer domain were made during Q3 2020 with the publication of a large prospective lung cancer study[5] supported by AstraZeneca, showing that Idylla™ reduces EGFR mutation testing turnaround time by more than a week, allowing faster patient management decisions[6]. Furthermore, Biocartis received a EUR 1.2 million grant from VLAIO[7] for the development of the Idylla™ GeneFusion Assay.
- *Infectious diseases* – On 10 August 2020[8], 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. EUA for this test is pending, but distribution continues per notification criteria in the US FDA's COVID-19 Policy[1]. Post the reporting period, on 10

November 2020, the CE-marked Idylla™ SARS-CoV-2 Test was successfully released to market in Europe. Biocartis also assumed further responsibility in responding to the COVID-19 pandemic by joining the COVID-19 Testing Industry Consortium led by Bristol-Myers Squibb Company[9] as announced on 1 October 2020. Finally, further progress was made on the SeptiCyte® RAPID[3] on Idylla™, resulting in the successful release of the CE-IVD marked version to the European market on 6 October 2020.

Partnerships highlights

- *Oncology partnerships:*
  - Partnership with GeneproDx – Post the reporting period, on 3 November 2020, Biocartis announced to have signed a license, development and commercialization agreement with GeneproDx, a molecular diagnostics company based in Santiago, Chile, for the development of GeneproDx's novel genomic test ThyroidPrint® on the Idylla™ platform. Under the terms of the agreement, GeneproDx will take the lead in the development of the Idylla™ ThyroidPrint® test, whereas Biocartis will be responsible for the distribution of the ThyroidPrint® on Idylla™ through its growing commercial infrastructure of Idylla™ instruments across the globe. ThyroidPrint® is a qRT-PCR[10] based mRNA-expression classifier[11] test that helps to determine whether a thyroid nodule with an indeterminate cytology result is benign or malignant[12]. A benign test result[13] allows physicians to recommend watchful waiting as an alternative to diagnostic surgery. This reduces exposing patients to surgical risks and permanent thyroid hormone supplementation. Moreover, it significantly reduces health costs associated with unnecessary surgery.
  - Partnership with Exact Sciences – Post the reporting period, on 29 October 2020, Biocartis and Genomic Health, Inc. (a subsidiary of Exact Sciences Corporation) announced to have agreed to terminate their collaboration, which was focused on the development of the Oncotype DX Breast Recurrence Score® Test and the Oncotype DX Genomic Prostate Score® (GPS™) Test on the Idylla™ platform. As a result of COVID-19, the project had been suspended earlier during 2020, with the project plan and timing under evaluation. The decision to terminate the collaboration was driven by the uncertain timing of a product market release because of the pandemic and a decision by Exact Sciences to shift priorities to other initiatives. As part of a termination settlement, Genomic Health, Inc. agreed to pay USD 12 million to Biocartis and license certain rights and transfer certain assets to Biocartis. The impact of the termination to Biocartis' future growth is contained, as the collaboration was limited to the European market. As such, the termination will have no impact on Biocartis' growth ambitions in the US and in RoW markets, nor will it affect the financial performance in 2020 other than as a result of the settlement.
- *Infectious diseases partnership:*
  - Partnership with Endpoint Health – Post the reporting period, on 3 November 2020, Biocartis announced it has entered into a partnership agreement with Endpoint Health, a Palo Alto, CA (USA) based company developing personalized care solutions and targeted therapies for critically ill patients. The partnership targets the development and commercialization of a novel companion diagnostic (CDx) test[14] on the Idylla™ platform and as such will further strengthen Biocartis' CDx business and infectious disease test menu alongside its core oncology offering on Idylla™. Under the terms of the agreement, Endpoint Health will lead the development and registration of the Idylla™ Endpoint test in interventional trials across a range of interventions including targeted immunotherapy and coagulation therapy indications. The parties intend to collaborate on the commercialization of the Idylla™ Endpoint CDx test, building on the growing worldwide commercial infrastructure of Idylla™ instruments.

Financial highlights

- *Cash position* – End of Q3 2020, Biocartis' cash position amounted to EUR 137 million (unaudited figure).
- *Extraordinary Shareholders' Meeting* – During the extraordinary shareholders' meeting held on 25 September 2020, the shareholders of the Company approved all agenda items, including the renewal of the authorization to the Board of Directors to increase the share capital of the Company by up to 20% of the then current amount during a period of one year.

Outlook

Provided that (a) the current global resurgence of COVID-19 cases does not lead to (i) widespread lock-down measures and (ii) a significant restriction of cancer patients' access to diagnostic testing, and (b) the Emergency Use Authorization ('EUA') of the Idylla™ SARS-CoV-2 Test is timely granted, Biocartis' guidance for 2020 is as follows:

- *Commercial cartridge volume:* Targeting a year-over-year commercial volume growth around 30%, representing a volume of Idylla™ cartridges around 228k;
- *Idylla™ installed base:* Targeting an installed base growth around 300 new Idylla™ instrument placements;

- *Idylla™ test menu outlook:*
    - ONCOLOGY MENU:

- Colorectal cancer menu – Subject to further feedback from US FDA interaction, US FDA 510(k) submission of the Idylla™ MSI Test is expected in Q4 2020 and US FDA submission of the PMA (Pre-Market Approval) application for the Idylla™ RAS tests is now expected in H1 2021 (instead of end 2020 initially);
- Lung cancer menu – RUO[15] launch of the Idylla™ GeneFusion Assay is expected in Q1 2021;

- INFECTIOUS DISEASE PARTNER MENU:

- The US FDA regulatory process, led by Immunexpress, is ongoing for the SeptiCyte® RAPID on Idylla™;
- Emergency Use Authorization ('EUA') with the US FDA of the Idylla™ SARS-CoV-2 Test is pending.
- *Cash position*: Targeted cash position in the range of EUR 120 million by 2020 year-end, an increase of EUR 10m from previous guidance as a result of the settlement payment following the termination of the collaboration with Genomic Health, Inc. announced on 29 October 2020.

Financial calendar 2021

- Early 2021 Reporting on Guidance 2020
- 25 February 2021 2020 full year results
- 1 April 2021 Publication 2020 annual report
- 22 April 2021 Q1 2021 Business Update
- 14 May 2021 AGM Biocartis Group NV
- 2 September 2021 H1 2021 results
- 10 November 2021 Q3 2021 Business Update

This afternoon at 15:00h CET/14:00 BST/09:00 EST, Biocartis is hosting a virtual Capital Markets Day for financial analysts, institutional investors and financial media. Biocartis will provide an update on its longer-term Idylla™ test menu strategy in oncology as well as in infectious diseases as a response to several important market trends that are believed to have a potential favorable impact on the Company's business. The webcast will be held in English. A recording of the webcast and supporting presentation will be available on the Company's investor relations website shortly after.