PRESS RELEASE

REGULATED INFORMATION
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BIOCARTIS Q3 2021 BUSINESS UPDATE

Mechelen, Belgium, 10 November 2021 – 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 2021 and the outlook for remainder of the year 2021.

Commenting on the Q3 2021 Business Update, Herman Verrelst, Chief Executive Officer of Biocartis, said: *"During Q3 2021, customer demand in oncology continued to grow strongly and was no longer disrupted by the pandemic in most parts of the world. This strong demand could however only be partly met because of the two-month production stop on our high-throughput cartridge manufacturing line, caused by the fire end of July. Customer orders were definitely there to maintain the growth rate of 96% we achieved in H1 2021, but limited production capacity confined cartridge volume growth to 29% in Q3 2021, and to 69% year-to-date. The shortage of reagents which already held us back in serving our customers' needs during the first half of the year, now also disrupts the replenishment of raw materials lost in the fire. The entire team is working hard to maximize production output and I believe that we are on track to significantly reduce the order backlog by the end of the year. Before the fire, we were on track to deliver record cartridge volume growth in 2021, but I am nevertheless proud that our outlook of 40% is still within reach, providing that reagent supply will allow us to produce as planned for the remainder of the year."*

Q3 2021 HIGHLIGHTS

- **Commercial cartridge volume:**
  - 29% commercial cartridge volume growth in Q3 2021 year-over-year and 69% growth year-to-date, despite the customer order backlog caused by the fire
  - Strongly growing demand in oncology across Europe, and a consistent contribution of the Idylla™ SARS-CoV-2 Test (CE-IVD) to total volumes
  - Confirmed recovery of oncology volumes in distributor markets[1] that recorded the strongest growth of all regions in Q3 2021
  - Steadily growing US cartridge volumes in oncology while basic Idylla™ SARS-CoV-2 Test volumes continue to come down
- **Idylla™ installed base:**
  - Installed base expansion on track, 43% more Idylla™ instruments placed year-over-year
  - Pace of new Idylla™ installations in the US is picking up after a slow H1 2021
- **Idylla™ test menu and partnerships:**
  - Successful CE-IVD launch of the Idylla™ SARS-CoV-2/Flu/RSV Panel on 2 September 2021
  - First Idylla™ SARS-CoV-2/Flu/RSV Panel (CE-IVD) cartridge volumes sold in European markets
- **Financial:**
  - End of Q3 2021, Biocartis' cash position amounted to EUR 64m (unaudited figure), not yet including insurance cover for damages caused by the fire

Commercial highlights

- *Commercial cartridge volume* – Global commercial cartridge demand continued to grow strongly but could only be partly fulfilled as a direct consequence of the fire incident of 30 July 2021. Cartridge manufacturing had to be suspended on the high-throughput manufacturing line 'ML2' for nearly two months. The time needed to replenish available stocks of raw materials still causes order backlogs across a variety of Idylla™ assays. Commercial cartridge volume in Q3 2021 nevertheless grew 29% year-over-year and average selling prices remained stable. Despite the customer order backlog, cartridge volume growth was particularly strong in Europe and in certain distributor markets where the pandemic impact on oncology testing is clearly fading out. As expected, the demand for the Idylla™ SARS-CoV-2 Test continued to reduce in the US[2]. In contrast, the demand for COVID-19 access testing in Europe with this Test remained robust, complemented by initial supply of the newly launched Idylla™ SARS-CoV-2/Flu/RSV Panel (CE-IVD).
- *Installed base* – The expansion of the Idylla™ installed base remained on track. The pace of new Idylla™ instrument placements picked up again in the US, compared to a slower H1 2021. Year-to-date Idylla™ instrument placements in Europe and in distributor markets are equally well ahead of 2020 numbers.
- *Regulatory update distributor markets* – During Q3 2021, the registration of the Idylla™ NRAS-BRAF Mutation Test (CE-IVD) and the Idylla™ KRAS Mutation Test (CE-IVD) was completed in Taiwan.

1 Defined as the world excluding European direct markets, US, China and Japan
2 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

Test menu and partnership highlights

- *Idylla™ SARS-CoV-2/Flu/RSV Panel* – Successful CE-IVD launch of the Idylla™ SARS-CoV-2/Flu/RSV Panel on 2 September 2021. The Panel detects SARS-CoV-2, Flu A/B and RSV nucleic acids in one single cartridge[3].

Organizational and operational highlights

- *Fire incident* – On 23 September 2021, Biocartis announced the restart of its high-throughput ML2 cartridge manufacturing line following the completion of the repairs and subsequent control and quality related procedures leading to the successful restart of the ML2 line in the night of 21 September 2021. Following a fire that broke out at one of the Company's warehouse facilities in Mechelen (Belgium) during the night of 30 July 2021, production on the ML2 line had been temporarily suspended. With the ML2 line now restarted, the Company is continuing efforts to secure the supply of certain assay-specific reagents, which remains a key condition for achieving the Company's commercial cartridge volume guidance of 40% growth in 2021 (see under 'Outlook').

Financial highlights

- *Cash position* – End of Q3 2021, Biocartis' cash position amounted to EUR 64m (unaudited figure), not yet including insurance cover for damages caused by the fire.

Outlook

The shortage of certain reagents caused by the pandemic is disrupting the timely replenishment of sufficient inventory. This still causes certain Idylla™ products to be temporarily unavailable to meet the entire customer demand, even after resuming production on the ML2 cartridge manufacturing line. Providing that this customer order backlog can be substantially reduced by the end of the year, Biocartis confirms its 2021 guidance at 40% growth target for its cartridge volumes:

- *Commercial cartridge volume:* Targeting a year-over-year growth of 40%, or commercial cartridge volumes of 320k. This is still subject to the timely availability of reagent raw materials for Idylla™ cartridges;
- *Installed base:* Targeting 300-350 new Idylla™ instrument placements;
- *Cash position:* Targeting at least EUR 50m cash position at year-end, provided timely collection of insurance claims related to the fire incident and potentially including a drawdown of available credit on the Company's multipurpose credit facility to rebuild sufficient safety stock of raw materials and finished products.

Financial calendar 2022

- 24 February 2022 2021 full year results
- 31 March 2022 Publication 2021 annual report
- 21 April 2022 Q1 2022 Business Update
- 13 May 2022 Annual General Shareholders' meeting Biocartis Group NV
- 1 September 2022 H1 2022 results
- 10 November 2022 Q3 2022 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/flu/RSV and sepsis. More information: www.biocartis.com. Follow us on Twitter: @Biocartis_.

3 And delivers results within approx. 90 minutes

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