PRESS RELEASE

REGULATED INFORMATION

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BIOCARTIS Q3 2019 BUSINESS UPDATE

Mechelen, Belgium, 14 November 2019 – 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 2019, post-period events and an outlook for the remainder of the year.

Key messages

- **Installed base:** Further installed base expansion across markets in Q3 2019, with US representing 40% of new Idylla™ instrument placements.
- **Cartridge volume:** Continued growth of commercial cartridge volumes predominantly driven by European and Rest of World (RoW[1]) markets. Year-over-year cartridge volume growth for Q3 2019 was 27%.
- **US commercialization:** Implementation of new US go-to market strategy resulting in successful customer transition from Fisher Healthcare to Biocartis, strengthening of the US direct sales team and actions implemented to address amongst others operational lessons learned in H1 2019.
- **Japan commercialization:** Nichirei Biosciences and Biocartis further progressed registration preparations for the Japanese market in Q3 2019. This resulted in a registration of the Idylla™ Instrument and Idylla™ Console with the Japanese Pharmaceuticals and Medical Devices Agency in October 2019 (post reporting period).
- **Menu expansion:** Progressed development of the liquid biopsy Idylla™ ctEGFR Mutation Assay (RUO[2]) during Q3 2019, resulting in a successful launch on 25 October 2019 (post reporting period).
- **Cash position:** Biocartis' cash position end Q3 2019 amounted to EUR 197m (unaudited figure).
- **Guidance**: Full year 2019 guidance reiterated.

Commenting on the Q3 business update, Herman Verrelst, Chief Executive Officer of Biocartis, said: *"Next to maintaining business performance in Europe and RoW markets, a key objective for our organization in Q3 2019 was to initiate the implementation of the new go-to market strategy for the US, aimed at facilitating a faster ramp-up of US cartridge volumes. As part of that implementation, all Idylla™ customers were successfully transitioned from Fisher Healthcare to Biocartis and our US sales organization was strengthened. The response from US customers was positive and supportive and an increasing number of them finalized their internal implementation activities, allowing them to start directing testing volumes to the Idylla™ platform. The implementation efforts for the US market are however still ongoing and will continue to be a focus area for Q4 2019. From a menu point of view, our teams made good progress in finalizing the development of a new liquid biopsy assay, the Idylla™ ctEGFR Mutation Assay[2] which we recently launched. With this assay, we continue to further expand our menu, key in the market adoption of our platform. I would also like to mention the progress we made in Japan where our partner Nichirei Biosciences successfully completed the registration of the Idylla™ platform, another milestone towards commercialization in that market. Q3 2019 has proven to be a rough patch of the road for Biocartis, but we believe that we are taking the right actions to drive further overall growth in the coming years."*

Commercial highlights

- *Installed base* – During Q3 2019, the installed base of Idylla™ instruments was further expanded in Europe, US, RoW and China. The new instrument placements in the US market accounted for 40% of the total installed base growth.
- *Commercial cartridge volume* – Continued growth in commercial cartridge volumes in Q3 2019, predominantly driven by European and RoW markets. This has resulted in a year-over-year volume growth of 27% for Q3 2019.
- *US commercialization* - Towards the end of Q3 2019, Biocartis initiated the execution of its announced new US go-to market strategy under which Biocartis' US direct sales team will drive commercialization going forward. The actions taken in that context resulted in:
  - Customer transition: All Idylla™ customers were successfully transitioned from Fisher Healthcare to Biocartis.
  - US sales team: The US sales team was strengthened through, amongst others, the implementation of a more regional focused management structure and continued education to accelerate Idylla™ implementation processes at US customers.

[1] RoW = Rest of the World. RoW is defined as the world excluding European direct markets, US, China and Japan
[2] Research Use Only, not for use in diagnostic procedures.

- Operational learnings: The actions taken to address the operational lessons learned in the US market were amongst others geared towards increasing US customer support with respect to the integration of Idylla™ within standard operational procedures, as well as the roll-out of US specific enhancements to the Idylla™ platform software.

Driven by amongst others the aforementioned, additional US customers completed their internal Idylla™ implementation process in Q3 2019, allowing them to start the actual transfer of testing volumes to the Idylla™ platform. Next to that, the US customer base was further expanded within the larger laboratory market segment and initial steps were taken to target the segment of regional pathology labs, which is expected to be a further key growth segment. In addition, several US customers published Idylla™ studies at the renowned AMP conference[3] (see below).

- *European commercialization* – European direct markets realized further growth in installed base and cartridge volume in Q3 2019, mainly driven by a continued growing use of Idylla™ in first line testing. The latter predominately by large laboratory customers in Western and Southern Europe.
- *RoW commercialization* – Biocartis' RoW distribution markets realized growth in cartridge volumes in Q3 2019 driven by the continued market penetration of distribution partners in larger geographies. Moreover, new market authorizations for the Idylla™ MSI Test were obtained in geographies such as Australia, Brazil and Thailand.
- *Japan commercialization* – Nichirei Biosciences Inc. ('Nichirei Bio.'), and Biocartis further progressed registration preparations for the Japanese market in Q3 2019. This resulted in a successful registration of the Idylla™ Instrument and Idylla™ Console with the Pharmaceuticals and Medical Devices Agency in Japan in October 2019 (post reporting period), an important milestone in the commercial strategy for Japan. Nichirei Bio. is scheduled to formally present the Idylla™ platform at the 58th annual meeting of the Japanese Society of Clinical Cytology in Okayama on 16 November 2019. In parallel, both partners are further progressing IVD-registration preparations for Idylla™ assays[4] in Japan.

Menu and partnership highlights

- *Launch Idylla™ ctEGFR Mutation Assay* – During Q3 2019, Biocartis further progressed the development of the Idylla™ ctEGFR Mutation Assay, resulting in a launch on 25 October 2019. The Idylla™ ctEGFR Mutation Assay (RUO) is the liquid biopsy version of the solid biopsy Idylla™ EGFR Mutation Test (CE-IVD) allowing for the detection of 49 EGFR mutations[5] directly from two ml of blood plasma and which provides results within approximately 160 minutes.
- *Idylla™ Oncotype DXx IVD Breast Recurrence Score™ Test* – During Q3 2019, Genomic Health and Biocartis progressed the development of the Idylla™ Oncotype DXx IVD Breast Recurrence Score™ Test and prepared for the placement of Idylla™ instruments at laboratories in Q4 2019 (beginning in France and Germany) to support the start of the validation studies for this test, which is expected in 2020.
- *European performance studies* – During Q3 2019, 10 new Idylla™ performance publications were issued in Europe, of which five papers[6] and five study abstracts. The five Idylla™ study abstracts were selected for publication at the renowned European Society for Medical Oncology ('ESMO') congress that took place between 27 September and 1 October 2019 in Barcelona (Spain). All Idylla™ studies published at ESMO 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, the Idylla™ MSI Assay (RUO[2]) and a prototype of the Idylla™ ctEGFR Mutation Assay. More information can be found in the press release here.
- *US studies* – Post the reporting period, Biocartis announced on 5 November 2019 the publication of five Idylla™ studies by US oncology key opinion leaders at the 'Association for Molecular Pathology' ('AMP') conference in the US[7]. The respective Idylla™ studies showed a strong performance of Idylla™ assays (RUO[2]) compared to other methods including IHC[8] and NGS[9] in terms of concordance[10], ease of use, workflow automation and turnaround times. Furthermore, some studies researched Idylla™'s capability to analyze different sample types[11] and smaller sample quantities. More information can be found in the press release here.

[3] The AMP (Association for Molecular Pathology conference) took place in Baltimore, Maryland (US), 7-9 November 2019
[4] For use as in vitro diagnostics
[5] Including insertions and deletions in exon 18, 19, 20 and 21 in the EGFR gene
[6] (1) Huang H et al. Evaluation, Validation, and Implementation of the Idylla™ System as Rapid Molecular Testing for Precision Medicine. J Mol Diagn. 2019 Sept. 21 (5); (2) Vallée A et al. Prospective evaluation of two screening methods for molecular testing of metastatic melanoma: Diagnostic performance of BRAF V600E immunohistochemistry and a NRAS-BRAF fully automated real-time PCR-based assay. PlosOne Aug 2019; (3) Evrard S et al. Multi-Center Evaluation of the Fully Automated PCR-Based Idylla™ EGFR Mutation Assay on Formalin-Fixed Paraffin-Embedded Tissue of Human Lung Cancer. Journal of Molecular Diagnostic. J Mol Diagn. 2019 Aug 21; (4) Van Haele M et al. Rapid clinical mutational testing of KRAS, BRAF and EGFR: a prospective comparative analysis of the Idylla™ technique with high-throughput next-generation sequencing. Journal of clinical pathology. J Clin Pathol. 2019 Jul 11; (5) Gilson P et al. Evaluation of KRAS, NRAS and BRAF hotspots mutation detection for patients with metastatic colorectal cancer using direct DNA pipetting in a fully-automated platform and Next-Generation Sequencing for laboratory workflow optimization. PlosOne Jul 2019
[7] AMP is the leading molecular diagnostics meeting that took place between 7-9 November 2019 in Baltimore, Maryland (US)
[8] Immuno-histochemistry is often used to assess the MSI status. MSI is useful for screening patients for Lynch syndrome, and has become a predictive marker for response to immunotherapy.
[9] Next-Generation Sequencing or NGS is a technology for determining the sequence of DNA or RNA to study for example specific genetic alterations in patients with cancer. Source: NCBI, Jan-Dec 2018, last consulted on 21 October 2019
[10] We refer to the abstracts for more details on https://doi.org/10.1016/S1525-1578(19)30391-5
[11] Incl. (un)extracted FFPE tissue, cytologic material, blood, bone marrow, aspirate smears and touch preparation tissue samples as well as NGS pre-capture libraries

Operational and financial highlights

- *Special Shareholder's Meeting* – On 27 September 2019 Biocartis held a special shareholders' meeting during which shareholders approved and ratified, in accordance with the Belgian Companies Code, certain provisions which come into effect at the moment a change of control occurs as set out in the terms and conditions of the convertible bonds that were issued on 9 May 2019.
- *Cash position* - Biocartis' cash position end Q3 2019 amounted to EUR 197m (unaudited figure).

Outlook

- *Menu outlook:*
  - Colorectal cancer menu – US market clearance for the Idylla™ MSI Test via a 510(k) submission to the US FDA along with the PMA[12] application for the Idylla™ RAS tests, subject to further feedback from the US FDA, is expected in 2020;
  - Lung cancer menu – Further development of the Idylla™ GeneFusion Panel towards expected launch in 2020; and
  - Breast cancer menu – Placement of Idylla™ instruments at European sites expected in Q4 2019, as a preparation for the clinical validation studies of the Idylla™ Oncotype DXx IVD Breast Recurrence Score™ Test, which are expected to start in 2020.
- *Full year 2019 guidance:* Expected full year installed base growth in the range of 325-350 Idylla™ instruments, full year increase in commercial Idylla™ cartridge volume in the range of 30%-35% and a targeted cash position in the range of EUR 170m -175m by year end.

Financial calendar 2020

- Early 2020 Reporting on Guidance 2019
- 5 March 2020 FY2019 results
- 2 April 2020 Publication Annual Report 2019
- 23 April 2020 Q1 2020 Business Update
- 8 May 2020 Annual General Shareholders' Meeting Biocartis Group NV
- 3 September 2020 H1 2020 results
- 12 November 2020 Q3 2020 Business Update

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More information:

Renate Degrave
Head of Corporate Communications & Investor Relations Biocartis
e-mail rdegrave@biocartis.com
tel +32 15 631 729
mobile +32 471 53 60 64

@Biocartis www.linkedin.com/Biocartis

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 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_.

[12] PMA = Pre-Market Approval

Forward-looking statements

Certain statements, beliefs and opinions in this press release are forward-looking, which reflect the Company's or, as appropriate, the Company directors' or managements' current expectations and projections concerning future events such as the Company's results of operations, financial condition, liquidity, performance, prospects, growth, strategies and the industry in which the Company operates. By their nature, forward-looking statements involve a number of risks, uncertainties, assumptions and other factors that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties, assumptions and factors could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward-looking statements contained in this press release regarding past trends or activities are not guarantees of future performance and should not be taken as a representation that such trends or activities will continue in the future. In addition, even if actual results or developments are consistent with the forward-looking statements contained in this press release, those results or developments may not be indicative of results or developments in future periods. No representations and warranties are made as to the accuracy or fairness of such forward-looking statements. As a result, the Company expressly disclaims any obligation or undertaking to release any updates or revisions to any forward-looking statements in this press release as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based, except if specifically required to do so by law or regulation. Neither the Company nor its advisers or representatives nor any of its subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this press release or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this press release.