PRESS RELEASE

REGULATED INFORMATION
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BIOCARTIS Q1 2019 BUSINESS UPDATE

Mechelen, Belgium, **25 April 2019 –** 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 2019, post-period events and an outlook for the remainder of the year.

Key messages

- Installed base: Continued installed base growth in Q1 2019 including crossing of the 1,000 installed base milestone.
- Cartridge volume: Continued growth in commercial cartridge volumes driven by European and Rest of World (RoW[1]) markets. Pick-up in US cartridge volumes expected in Q2 and Q3 2019.
- Commercial footprint: On 7 January 2019, the signing of a commercialization agreement with Nichirei Bioscience for the Japanese market was announced. Consequently, Biocartis' commercial network now covers all major molecular diagnostics markets worldwide.
- MSI testing: CE-IVD launch of the Idylla™ MSI Test on 28 February 2019, a key addition to the Idylla™ colorectal cancer (CRC) test menu as MSI detection is currently recommended for all patients with CRC[2].
- Immuno-oncology partnership: Bristol-Myers Squibb Company and Biocartis announced the signing of a collaboration agreement for MSI testing with immuno-oncology therapies on 12 March 2019.
- Equity raise: Successful EUR 55.5m private placement of new shares on 23 January 2019.
- Cash position: Biocartis' cash position at the end of Q1 2019 amounted to EUR 100m (unaudited figure). No drawdowns were made on the Company's multiple purpose credit facility of EUR 27.5m as per end of Q1 2019.
- Guidance: Full year 2019 guidance reiterated.

Commenting on the Q1 business update, Herman Verrelst, Chief Executive Officer of Biocartis, said:
"We started 2019 with a good first quarter in which we made progress on all fronts: commercialization, menu expansion, manufacturing, financing and organization. We now have the foundations for a global commercial footprint in place, supporting the further global roll-out of our platform. With BMS, we added an important pharma partner to the Idylla™ eco-system, supporting our move into the immuno-oncology space. We CE-marked another significant test in our menu and updated our menu strategy. We initiated the commercial manufacturing transfer of Idylla™ cartridges to a newly installed production line that is expected to generate significant cost efficiencies over the coming years. We managed to raise EUR 55.5m in a challenging equity markets environment, providing us with a solid cash position. Finally, we are strengthening our management team with two seasoned executives who bring in-depth industry expertise to further support us in the scaling of our organization."

Commercial update

- *Installed base* – Continued installed base growth realized across all markets in Q1 2019. Also, an important milestone was reached in the global commercial roll-out of the Idylla™ platform by placing the 1,000th Idylla™ instrument with the Diagnostic Medicine Institute at Geisinger, one of the largest health service organizations in the US.
- *Cartridge volumes* – Continued growth in commercial cartridge volumes that was driven by European and RoW markets. An accelerated ramp-up of US commercial cartridge volumes is expected in Q2 and Q3 2019.
- *European commercialization* – Installed base growth driven by increased capacity demand at existing customers that moved Idylla™ to first line testing as well as the addition of new customers, especially in France. Cartridge volume growth realized across all geographies with the highest growth rates realized in France, Italy and the UK.
- *US commercialization* – Continued expansion of the US customer base, especially within the larger top segment where Idylla™ is seen as complementary to their next generation sequencing (NGS) workflows as well as an

[1] RoW = Rest of the World. RoW is defined as the world excluding Europe, US, China and Japan
[2] Source: NCCN Guidelines, https://www.nccn.org/patients/guidelines/colon/22/, last consulted on 23 April 2019

ultra-rapid solution for applications where fast and actionable results are key. An accelerated ramp-up of US cartridge volumes due to more routine cartridge orders of existing and new US customers is expected in Q2 and Q3 2019.

- *RoW commercialization* – A large number of co-visits with distributors to large accounts and several well attended events organized by pharma partners featuring Idylla™ in key RoW markets resulted in the addition of new customers and a healthy pipeline of new installations for the remainder of the year. Existing installed base in RoW markets was increasingly used for routine testing, supporting further cartridge volume growth.
- *China commercialization* – Completion of the closing of the joint venture with Wondfo ('JV') in Q1 2019 resulted in the first capital contribution by both partners and subsequently the payment by the JV of a license fee to Biocartis. Furthermore, core JV employees were hired and continued recruitment is geared towards product registration filings, with a first focus on MSI testing and the establishment of local manufacturing capabilities. Several initial Idylla™ placements were realized at Chinese customers in Q1 2019.
- *Japan commercialization* – On 7 January 2019, Biocartis announced to have signed an agreement with Nichirei Bioscience, a leading supplier of biological and diagnostics products in Japan, for the product registrations and distribution of the Idylla™ platform in Japan. Upon successful registration, Nichirei Bioscience's sales force will commercialize the Idylla™ platform across its network of some 2,000 pathology laboratories.
- *Covance agreement* – Post the reporting period, on 23 April 2019, Biocartis announced the global strategic commercialization agreement with Covance, LabCorp's Drug Development business, aimed at offering the Idyllla™ platform and its existing Idylla™ oncology assay menu to Covance's customer base, and the placement of several Idylla™ instruments at Covance sites in the US and China[3].

Menu and partnership highlights

- *MSI CE-IVD launch* – On 28 February 2019, Biocartis announced the CE-IVD marking of its fully automated Idylla™ MSI Test. MSI testing today is recommended for all colorectal and endometrial cancers[4] but is still underused since current methods are highly complex. The Idylla™ MSI Test has been developed to overcome these drawbacks. It is a fully automated test that provides information on the MSI status[5] (i.e. Microsatellite Instability-High (MSI-H) or Microsatellite Stable (MSS)) of colorectal cancer (CRC) tumors within approximately 150 minutes from just one slice of FFPE[6] tumor tissue, without the need of a reference sample. The test[7] shows high concordance (>97%) and lower failure rates compared to standard methods. The unique aspects of the Idylla™ MSI Test could enable a broader penetration of MSI testing, and could make this test a key addition to Biocartis' Idylla™ CRC test menu.
- *BMS immuno-oncology collaboration* – On 12 March 2019, Bristol-Myers Squibb Company (NYSE: BMY), a global biopharmaceutical company, and Biocartis announced the signing of a collaboration agreement focused on MSI testing in connection with immuno-oncology therapies. Bristol-Myers Squibb's Opdivo® (nivolumab) plus low-dose Yervoy®[8] (ipilimumab) is the first immuno-oncology combination treatment approved by the US Food and Drug Administration (FDA) for MSI-High or mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC) that has progressed following treatment with certain chemotherapies[9]. The collaboration agreement allows for joint developments and registrations of the Idylla™ MSI test for use in a variety of indications, commercial settings and geographies. The first focus under the agreement is expected to be the registration in the US of the Idylla™ MSI test as a companion diagnostic[10] (CDx) test in mCRC.
- *USCAP Idylla™ studies* – A total of six Idylla™ studies were presented by four different US customers at the United States and Canadian Academy of Pathology ('USCAP') Annual Meeting in Maryland, US, from 16-21 March 2019:
    - Dartmouth Hitchcock Medical Center: a CRC focused prospective study and a melanoma focused study with comparison to NGS;

[3] Idylla™ Assays currently available in the USA and China are for Research Use Only, not for use in diagnostic procedures. Any support of clinical trials in the USA, China, or other locations will follow applicable regulations
[4] Source: ASCO guidelines, www.asco.org/endorsements/HereditaryCRC
[5] Clinical Performance Study showed 99.7% concordance for MSI testing vs Promega (unpublished data); De Craene et al. (2018) Journal of Clinical Oncology 36:15 suppl, e15639; De Craene et al. (2017) Annals of Oncology 28 (suppl_5): v209-v268; Maertens et al. (2017) Annals of Oncology 28 (suppl_5): v22-v42
[6] FFPE = formalin fixed, paraffin embedded
[7] The Idylla™ MSI Test uses a new set of short homopolymers located in the ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A & SULF2 genes, which were exclusively licensed to Biocartis in 2013 from VIB, the life sciences research institute in Flanders (Belgium), and originated from the research of the group of Prof. Diether Lambrechts (VIB-KU Leuven, Belgium). These MSI biomarkers are tumor-specific, show a high frequency in colorectal and endometrial cancers and are stable across different ethnicities ensuring excellent specificity of the assay
[8] 3 mg/kg Opdivo® plus 1 mg/kg Yervoy®
[9] Treatment with fluoropyrimidine, oxaliplatin and irinotecan
[10] 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

- Medical College of Wisconsin: a CRC focused study with comparison to PCR[11] and IHC[12] for Microsatellite Instability Status and a multiple cancers focused study using challenging FFPE samples not suitable for conventional sanger and NGS testing;
- Memorial Sloan Kettering Cancer Center: a hairy cell leukemia focused study using different sample types including stained smear slides, blood and bone marrow without pre-extraction; and
- Wake Forest Baptist Health: a melanoma focused study using pigmented melanomas.

The posters of the referenced studies can be found here.

- *European Idylla™ studies* – In Q1 2019, two additional Idylla™ studies by European customers were published:
  - Université de Lorraine[13], Nancy, France: retrospective study on mCRC FFPE samples that showed that Idylla™ was able to generate results for 75% of samples for which the DNA quality was identified as too low for NGS testing. Of the generated results, 40% showed a mutation with a direct clinical impact on patient management; and
  - Sapienza University of Rome[14], Rome, Italy: prospective study, aiming to investigate the extent of conversion to RAS wild type disease in plasma at the time of progression and to explore whether the conversion to a wild type RAS status in plasma might be exploitable for therapeutic purpose.

Organizational and financial update

- *Management team* – In light of the Company's further international growth, expansion of its partner network and associated scaling of the organization, several changes to the Company's management team are effectuated:
  - Appointment Chief Operating Officer – Piet Houwen joined Biocartis as its Chief Operating Officer in April 2019. With more than 25 years in various operational and general management roles, Piet Houwen has a strong track record in manufacturing, process engineering, project and people management. Piet Houwen has gained broad operational experience in dynamic international environments, including in fast moving consumer goods, food manufacturing, bio-pharmaceuticals and consulting. Prior to joining Biocartis, Piet Houwen was Chief Operations Officer at Ablynx and prior to that, he held global roles for Sanofi/Genzyme and Janssen Pharmaceutica (part of Johnson & Johnson family of companies) where he was active in pharmaceutical manufacturing of large and small molecules, stent coating and medical devices. Piet Houwen holds a Master's Degree in Mechanical Engineering from the Delft University of Technology (The Netherlands).
  - Appointment Global Head Pharma Collaborations and Partnering – Dirk Zimmermann will join Biocartis in May 2019 as Global Head of Pharma Collaborations and Partnering. Dirk Zimmermann has a profound expertise in blood screening, as well as in oncology and respective companion diagnostics, and a strong track record in molecular diagnostics product development, spanning from integrated PCR systems to NGS workflows and applications. Prior to joining Biocartis, Dirk Zimmermann held positions at Roche Diagnostics (SWX: ROG) and QIAGEN (SE: QGEN) in product development and corporate venturing. Dirk holds an Executive MBA of IMD (Switzerland), a PhD from the Max Planck Institute of Biophysics (Germany), and a Master's degree in Chemistry from the University Göttingen (Germany).
  - Changes in the Chief Commercial Officer role – Biocartis and Hilde Eylenbosch, the Company's Chief Commercial Officer, have agreed to terminate their collaboration as per the end of April 2019. No immediate appointment of a new CCO is envisaged as the tasks of the current CCO will be redistributed to the Company's CEO and senior commercial management.
- *Cartridge manufacturing* – End of 2018, Biocartis completed the validation of its second cartridge manufacturing line that should provide for an additional annual cartridge capacity of over 1 million Idylla™ cartridges. In Q1 2019, Biocartis initiated the transfer process of the production of its high-volume commercial tests to this new cartridge manufacturing line.
- *Equity raise* – On 23 January 2019, Biocartis announced that it successfully raised an amount of EUR 55.5m in gross proceeds by means of an over-subscribed private placement via an accelerated bookbuild offering.
- *Cash position* - Biocartis' cash position at the end of Q1 2019 amounted to EUR 100m (unaudited figure). No drawdowns were made on the Company's multiple purpose credit facility of EUR 27.5m as per end of Q1 2019.

[11] Polymerase Chain Reaction
[12] Immunohistochemistry
[13] Franczak C et al. Integrated routine workflow using next-generation sequencing and a fully-automated platform for the detection of KRAS, NRAS and BRAF mutations in formalin-fixed paraffin embedded samples with poor DNA quality in patients with colorectal carcinoma. PLoS One. 2019 Feb 27;14(2):e0212801. doi: 10.1371/journal.pone.0212801. eCollection 2019, https://www.ncbi.nlm.nih.gov/pubmed/30811471
[14] Raimondi et al. Transient Disappearance of RAS Mutant Clones in Plasma: A Counterintuitive Clinical Use of EGFR Inhibitors in RAS Mutant Metastatic Colorectal Cancer. Cancers (Basel). 2019 Jan 4;11(1). pii: E42. doi: 10.3390/cancers11010042, https://www.ncbi.nlm.nih.gov/pubmed/30621206

Outlook

- *Menu expansion:*
  - Colorectal cancer menu – 510(k) submission of the Idylla™ MSI Assay documentation with the US FDA is expected in 2020. Submission of Idylla™ RAS PMA[15] documentation with the US FDA, subject to further feedback from US FDA interactions is expected in 2020;
  - Lung cancer menu – Launch of a liquid biopsy version of the Idylla™ EGFR Mutation Assay (RUO[16]) expected in H2 2019. Further development of the Idylla™ GeneFusion Panel towards expected launch in 2020; and
  - Breast cancer menu – Placement of Idylla™ instruments at European sites for the clinical validation studies of the Idylla™ Oncotype DXi IVD Breast Recurrence Score™ test in H2 2019.
- *Full year 2019 guidance reiterated* – Expected full year installed base growth of 350 Idylla™ instruments, year-over-year increase in commercial Idylla™ cartridge volumes of around 60%-70% and a targeted cash position in the range of EUR 55m – EUR 65m by year end, excluding drawdowns on the Company's multiple purpose credit facility.

Financial calendar 2019

- 10 May 2019 Annual General Shareholders' Meeting Biocartis Group NV
- 5 September 2019 H1 2019 results
- 14 November 2019 Q3 2019 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 rapidly expanding test menu addressing key unmet clinical needs in oncology. This area 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. Press Photo Library available here. Follow us on Twitter: @Biocartis_.

Forward-looking statements

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[15] PMA = Pre-Market Approval
[16] Research Use Only, not for use in diagnostic procedures

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