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Biocartis Group NV: BIOCARTIS Q3 2018 BUSINESS UPDATE

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BIOCARTIS Q3 2018 BUSINESS UPDATE

Mechelen, Belgium, **15 November 2018 -** 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 2018, post-period events and an outlook for the remainder of the year.

Key messages

- Installed base: Continued strong installed base growth in Q3 2018, US contributing to the majority of new Idylla(TM) placements. Guidance for the full year increased to 300 new instrument placements.
- Cartridge volume: Commercial cartridge volume for the first nine months of 2018 doubled year-over-year. Guidance for the full year is narrowed to 130,000 - 135,000 commercial cartridges (approx. 90% increase year-over-year).
- MSI testing: Promising initial market adoption of the Idylla(TM) MSI Assay, launched as RUO[1] on 17 July 2018.
- China strategy: Joint venture with Wondfo, a fast growing diagnostics leader in China, announced on 3 September 2018, for the commercialization of the Idylla(TM) platform and molecular diagnostics oncology products in mainland China.
- Cash position: Biocartis' cash position at the end of Q3 2018 amounted to EUR 81m (unaudited figure). No drawdowns were made on the Company's multiple purpose credit facility of EUR 27.5m as per end of Q3 2018. Guidance for targeted year-end cash position now set at around EUR 55m.

Commenting on the Q3 business update, Herman Verrelst, Chief Executive Officer of Biocartis, said: *"During Q3 2018, we further executed on our commercial strategy to roll-out the Idylla(TM) platform in key worldwide markets. We are pleased with the progress we made in Europe, the US and our RoW[2] markets and are happy that we could announce the joint venture in China with Wondfo. The latter is an important first step towards commercialization in that market. In addition, we have seen a good initial market adoption of our innovative Idylla(TM) MSI Assay[3], and we are on track for a CE-marking of that assay early next year. Another highlight in Q3 is the ever-increasing body of scientific and clinical performance data on the Idylla(TM) platform. In addition, we saw the publication of a series of strong Idylla(TM) performance studies conducted by key opinion leaders presented at the ESMO conference in Europe and the AMP meeting in the US."*

Commercial update

- *Installed base* - Q3 2018 showed a solid number of new Idylla(TM) placements of which the vast majority was placed in US and European markets.
- *Cartridge volume* - Driven by continued cartridge volume growth in European and RoW[2] markets, cartridge volume for the first nine months of 2018 doubled year-over-year.
- *European commercialization* - Successful continued efforts focused on increased cartridge consumption at existing clients helped fuel strong cartridge volume growth on the existing European installed base. Additional volume growth among existing clients was realized with the launch of the Idylla(TM) MSI

Assay (RUO[1]). This test also triggered the adoption of the Idylla(TM) platform with new European clients.

- *US commercialization* - The continued expansion of the US direct sales team in combination with the Fisher Healthcare sales team, along with new publications of US Idylla(TM) performance studies, supported a strong further growth of the US installed base in Q3 2018. Ongoing validation efforts by our clients will lead to cartridge consumption towards year-end, adding material volume as of 2019. Furthermore, as feedback from US Key Opinion Leaders (KOLs) on the Idylla(TM) MSI Assay (RUO[1]) has been very positive, this test is expected to be an important driver in the further near term US market adoption of the Idylla(TM) platform.
- *China commercialization* - On 3 September 2018, Biocartis and Guangzhou Wondfo Biotech Co., Ltd. ('Wondfo', SHE: 300482), a fast growing diagnostics leader in China, announced entering into a joint venture aimed at the commercialization of the Idylla(TM) platform in mainland China, within the field of oncology. The joint venture will be 50% owned by Biocartis and 50% owned by Wondfo. The initial activities of the joint venture are focused on the local manufacturing, commercialization and registration with the Chinese Regulatory Authorities (CFDA) of the existing products in the Idylla(TM) molecular diagnostics oncology test menu for amongst others colorectal and lung cancer. This is a first important step in unlocking Idylla(TM)'s commercial potential in the Chinese molecular diagnostics market, being one of the fastest growing in the world and expected to reach a total value of USD 1.5bn by the end of 2022[3].
- *Distribution markets RoW*[2] - During Q3 2018, Biocartis obtained additional market authorizations for its products in several Latin American, North African and Asian markets. These new market authorizations, as well as the strategy to focus on those RoW[2] geographies that are of interest to pharmaceutical partners, have enabled further continued cartridge volume growth in Q3 2018.

Menu highlights

- *Launch Idylla(TM) MSI Assay (RUO[1])* - On 17 July 2018, Biocartis launched its innovative Idylla(TM) MSI Assay (RUO[1]) that provides information on the MSI status[4] (i.e. MSI-High or Microsatellite stable) of a tumor within approximately 150 minutes from just one slice of FFPE[5] tumor tissue, without requiring a reference sample. This fully automated Idylla(TM) MSI Assay (RUO)[1] includes a novel set of seven exclusively licensed MSI biomarkers, consisting of short homopolymers located in the ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A and SULF2 genes. Several multi-center studies[4] comparing the standard methods[6] with the Idylla(TM) MSI Assay (RUO[1]) showed a >95% concordance between results. Furthermore, compared to standard methods, the Idylla(TM) MSI Assay[1] has a significantly lower failure rate[4], provides automated result reporting and includes MSI-specific pan-tumor biomarkers, independent of ethnicity[4]. Once validated for diagnostic use, the test is expected to significantly strengthen Biocartis' colorectal cancer test menu and since MSI is an independent factor that may predict a patient's response to certain immunotherapies[7], it provides Biocartis with further opportunities to enter into the field of immuno-oncology.
- *License Rights EGFR Ectodomain Mutations* - On 28 August 2018, Biocartis announced that it has obtained exclusive worldwide license rights for highly innovative EGFR ectodomain mutations that have shown to determine response to targeted therapy for patients with metastatic colorectal cancer (mCRC)[9]. The new agreement is a conversion of two existing agreements with Hospital Del Mar (Barcelona, Spain) and inventors Dr. Bardelli and Dr. Arena from the University of Torino (Torino, Italy) in relation to two patent families of EGFR ectodomain mutations. Biocartis is now entitled to sublicense the licensed rights to third parties.
- *US Idylla(TM) performance study at AACC* - On 31 July 2018, Biocartis announced that a study abstract[8] on the performance of the Idylla(TM) KRAS and NRAS-BRAF-EGFR492 Mutation Assays compared with Next Generation Sequencing (NGS) using colorectal cancer (CRC) tissue samples was selected for oral presentation at the 70th AACC (American Association for Clinical Chemistry) Annual Scientific Meeting in Chicago, IL (US). In the study, 44 archived FFPE colorectal cancer (CRC) tissue samples previously analyzed by NGS[9] were tested on Idylla(TM). The Idylla(TM) platform successfully detected all of the target KRAS, NRAS and BRAF mutations previously identified by the NGS method, resulting in an Idylla(TM) sensitivity of 100%. Analysis of the control samples[10] demonstrated agreement for all sample results with 100% reproducibility. The study concluded that the Idylla(TM) platform offers reliable and sensitive testing of mutations in KRAS, NRAS and BRAF directly from FFPE tumor tissue sections, and that it may complement NGS and other molecular testing systems at larger diagnostic centers by providing significantly faster turnaround times through its simplicity and ease of use.
- *Post-period Idylla(TM) performance studies*:
    - ESMO presentations - On 19 October 2018, Biocartis announced that two studies, one treatment outcome study[11] on the Idylla(TM) ctKRAS and ctNRAS-BRAF Mutation Tests (CE-

IVD) and one[12] on the performance of the prototype Idylla(TM) MSI test, had been selected for presentation at the renowned European Society for Medical Oncology (ESMO) congress. The first study[11] that was presented is an analysis of two prospective clinical trials[13] on anti-EGFR treatment in metastatic colorectal cancer (mCRC), and is a first in its kind to demonstrate the clinical impact of the liquid biopsy Idylla(TM) ctKRAS and ctNRAS-BRAF Mutation Tests (CE-IVD). The second study[12] revealed excellent performance of the prototype Idylla(TM) MSI test based on overall high concordance compared to other testing methods frequently used in today's clinical practice[14].

- AMP abstracts - On 1 November 2018, Biocartis announced the publication of eight Idylla(TM) performance study abstracts at the Association for Molecular Pathology ('AMP') conference. The studies are performed by renowned US oncology key opinion leaders from the Memorial Sloan Kettering Cancer Center (New York), Dartmouth-Hitchcock Medical Center (New Hampshire), AstraZeneca and the University of Alabama. All abstracts again highlight excellent Idylla(TM) performance, showing high concordance with current testing methods in combination with the unique features of the Idylla(TM) platform, being its ease of use, fully automated workflow and short turnaround times.

Organizational and financial update

- *Cartridge manufacturing* - During Q3 2018, Biocartis progressed the validation of and completed successful manufacturing runs on Biocartis' second cartridge manufacturing line that should provide for an additional annual cartridge capacity of over 1 million Idylla(TM) cartridges. The aim is to start commercial cartridge production on this line by year-end.
- *Cash position* - Biocartis' cash position at the end of Q3 2018 amounted to EUR 81m (unaudited figure). No drawdowns were made on the Company's multiple purpose credit facility of EUR 27.5m as per end of Q3 2018.

Menu news flow

- Capital Markets Day - On 28 February 2019, Biocartis will host a Capital Markets Day in its headquarters in Mechelen, Belgium tailored for institutional investors, research analysts and sector journalists to provide amongst others an update on the Company's Idylla(TM) test menu strategy.
- Biocartis, in consultation with its partners, continuously re-prioritizes resources across the portfolio of development projects to further optimize the ramp-up of cartridge volumes and execution of pharmaceutical and test content partnerships, impacting in certain cases project timings:
  - Colorectal cancer: As stated in earlier communications, CE-IVD marking of the Idylla(TM) MSI Assay[1] in Q1 2019. In consultation with our partner Amgen, the submission of the Idylla(TM) RAS PMA (Pre-Market Approval[15]) documentation with the US FDA is now set towards end 2019, subject to further feedback from US FDA interactions.
  - Lung cancer: As stated in earlier communications, launch of a liquid biopsy version of the Idylla(TM) EGFR Mutation Test in H1 2019.
  - Breast cancer: Launch of the Oncotype DXi IVD Breast Recurrence Score(TM) test on the Idylla(TM) platform, developed by Genomic Health Inc. in collaboration with Biocartis, is planned in H2 2019. For the breast cancer resistance monitoring test, currently under development by Biocartis and its partner LifeArc, it was decided to, based on recent discussions with key opinion leaders, make certain changes to the product definition to increase the clinical and market value of this assay. As a consequence the development and release timelines are pushed out beyond 2019.

Updated 2018 guidance

- *Installed base* - Guidance on new instrument placements for 2018 now set at 300, up from the previously communicated top end of the 250 - 275 range.
- *Cartridge volume* - Guidance on year-over-year cartridge volume growth is narrowed to 130,000 - 135,000 commercial cartridges (approx. 90% year-over-year growth), close to our ambitious guidance of doubling year-over-year.
- *Cash position* - Targeted year-end cash position further narrowed to around EUR 55m, excluding drawdowns on the Company's multiple purpose credit facility.

Financial calendar 2019

- 2018 full year results - 28 February 2019
- Publication 2018 annual report - 4 April 2019

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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(TM) system 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 launched the Idylla(TM) system in September 2014. Biocartis is developing and marketing a rapidly expanding test menu addressing key unmet clinical needs in oncology and infectious diseases. These areas represent respectively the fastest growing and largest segments of the MDx market worldwide. Today, Biocartis offers fifteen oncology assays and two infectious disease assays in Europe. More information: www.biocartis.com. Press Photo Library available here. Follow us on Twitter: @Biocartis_.

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. 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.

[1] Research Use Only, not for use in diagnostic procedures.

[2] RoW = Rest of the World. RoW is defined as the world excluding Europe, US, China and Japan.

[3] Source: DataMintelligence, "Global Molecular Diagnostics Market 2018-2025"

[4] Maertens G. et al. Annals of Oncology (2017) 28 (suppl_5): v22-v42; De Craene B. et al. Annals of Oncology (2017) 28 (suppl_5): v209-v268; De Craene et al. J Clin Oncol 36, 2018 (suppl; abstr e15639)>.

[5] Formalin fixed, paraffin embedded.

[6] Including IHC and Promega MSI analysis system 1.2.

[7] ESMO (ESMO consensus guidelines for the management of patients with metastatic colorectal cancer. Annals of Oncology 0: 1-37, 2016). NCCN (NCCN Clinical Practice Guidelines in Oncology - Colon Cancer - Version 2.2016). ASCO (Allegra C.J. et al. Extended RAS gene mutation testing in metastatic Colorectal Carcinoma to predict response to antiepidermal growth factor receptor monoclonal antibody therapy: American Society of Clinical Oncology Provisional Clinical Opinion Update 2015. Journal of Clinical Oncology 2016; 34(2):179-85) and CAP/AMP/ASCO.

[8] M. Rabie Al-Turkmani et al., "Rapid Somatic Mutation Testing in Colorectal Cancer Using a Fully Automated System and Single-Use Cartridge: A Comparison with Next-Generation Sequencing", first presented at 70th AACC Annual Scientific Meeting in Chicago, IL (US).

[9] Using the Ion AmpliSeq 50-gene Cancer Hotspot Panel v2 (Thermo Fisher Scientific).

[10] Horizon mutated samples.

[11] Montagut et al., "Clinical impact of circulating tumor RAS and BRAF mutation dynamics in metastatic colorectal cancer patients treated with first-line chemotherapy plus anti-EGFR therapy: Combined analysis of two prospective clinical trials", first presented at ESMO, 19-23 October 2018, Münich, Germany, and published in the ESMO 2018 Congress Abstract Book, a supplement to the official ESMO journal Annals of Oncology.

[12] De Craene et al., "Detection of microsatellite instability (MSI) with a novel set of 7 Idylla(TM) biomarkers on colorectal cancer samples in a multi-center study", first presented at ESMO, 19-23 October 2018, Münich, Germany, and published in the ESMO 2018 Congress Abstract Book, a supplement to the official ESMO journal Annals of Oncology.

[13] PULSE and POSIBA studies performed by the GEMCAD group.

[14] Repeat length with this set of biomarkers was determined on 333 formalin fixed and paraffin-embedded (FFPE) colorectal cancer (CRC) samples using Idylla(TM) MSI Assay prototype cartridges, which allow a fully automated workflow including sample preparation, DNA amplification and automated repeat length calling. Consecutive analysis of 182 samples revealed a higher number of valid results for Promega (3.8%) and IHC (13.2%) compared to the prototype Idylla(TM) MSI Assay (2.2%). A neural network based algorithm was built on a large cohort of reference/patients samples (n>3000) obtained from different clinical sites (n>10) and different ethnic groups (n one-forth 5). Three-hundred fourteen samples were characterized by means of the Promega MSI analysis system and 272 samples by means of MMR protein IHC staining. Approximately 30% of the samples included in the study were previously characterized to be MSI-H by either one of these methods.

[15] Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. PMA is the most stringent type of device marketing application required by FDA. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s). Source: https://www.fda.gov/medicaldevices/deviceregulationandguidance/ howtomarketyourdevice/premarketsubmissions/premarketapprovalpma/, last consulted on 7 November 2018.