PRESS RELEASE REGULATED INFORMATION

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BIOCARTIS Q3 2016 BUSINESS UPDATE

KEY MESSAGES

- **Continued strong ramp-up in commercial Idylla™ cartridge consumption: Q3 2016 consumption equals entire commercial consumption in H1 2016**
- **Guidance of installed base growth for 2016 at top end of the 150-175 range reiterated**
- **Important CE-marking of Idylla™ NRAS-BRAF Mutation Test (solid biopsy) expected before year-end**
- **Guidance of year-end cash position of around EUR 50m, in line with previously guided range**
- **Signing of U.S. distribution agreement with Thermo Fisher Scientific**

Mechelen, Belgium, **17 November 2016 –** 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 2016, selected post period events and an outlook for the remainder of the year.

Commenting on the business update, Rudi Pauwels, Chief Executive Officer of Biocartis, said: *"The third quarter of this year demonstrated promising continued market adoption of our Idylla™ platform and tests. I am pleased to see that every day more and more patients are being helped with our solutions in Europe and in our distribution markets. I really look forward to start our commercialization efforts in the U.S. together with our partner Thermo Fisher Scientific, who offers us access to a powerful sales network and deep knowledge of that market. Having a presence in the U.S. strongly adds to our ambition of impacting the global market for molecular diagnostic testing."*

Commercial update

Biocartis commercializes its proprietary molecular diagnostics platform Idylla™ via direct representations in key European countries and via distribution partners in other geographies.

- *Installed base:* The third quarter of 2016 showed a continued expansion of our installed base of Idylla™ instruments. Based on the installed base end of H1 2016 of over 270 Idylla™ instruments, the additions in Q3 2016 and outlook for Q4 2016, the installed base is expected to be around 340 Idylla™ instruments by year end.
- *Cartridge consumption:* Following continued installed base growth and menu expansion, commercial Idylla™ cartridge consumption in Q3 2016 was equal to the entire commercial cartridge volume for the first six months of 2016.
- *Commercial footprint:* During Q3 2016 Biocartis further expanded its global commercial footprint with the signing of several new distribution agreements in amongst others Southeast Asia. Furthermore, Biocartis obtained key market authorizations in Latin America (Brazil and Colombia).
- *U.S. partnership:* Discussions on a U.S. partnership for the commercialisation of Idylla™ were advanced in Q3, resulting in the deal with Thermo Fisher Scientific announced on 17 November 2016 as described below.

Idylla™ test menu update

During Q3 2016, Biocartis further advanced the development of new tests for its Idylla™ platform:

- *Solid biopsy oncology menu*: Biocartis continued the work on required validation studies for the CE-marking of its Idylla™ NRAS-BRAF solid biopsy test in Q3 2016. Once obtained (expected before year-end), Biocartis will be able to offer its customers a complete RAS-BRAF solid biopsy analysis for clinical use in the field of colorectal cancer testing. It is unique that both these tests allow for 'same day results'. Colorectal cancer is in the top three of most prevalent cancers worldwide[1], which makes this CE-marking an important driver for the

[1] Source: http://www.wcrf.org/int/cancer-facts-figures/worldwide-data

further market adoption of Idylla™, also supported by the inclusion of a joint RAS-BRAF analysis in the ESMO[2] guidelines as of July 2016. Furthermore, during Q3 2016, validation studies have been initiated for the CE-marking of the Idylla™ EGFR Mutation Assay (lung cancer). This CE-marking is expected for beginning of 2017 and will complete the required CE-markings for all the solid biopsy tests that are included in Biocartis' core menu for oncology (i.e. tests for melanoma, colon and lung cancer).

- *Liquid biopsy oncology menu:* The development of liquid biopsy versions (RUO[3]) of the Idylla™ KRAS Mutation Assay and the Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay, as part of the collaboration signed with Merck KGaA in January 2016, was further progressed in Q3 2016. The launch of the Idylla™ ctKRAS Mutation Assay is expected before the end of 2016 and launch of the Idylla™ ctNRAS Mutation Assay in early 2017.
- *U.S. 510k submission file:* Biocartis and its partner Janssen Diagnostics made good progress during the third quarter on the finalisation work for the U.S. FDA 510k submission file[4] of the Idylla™ Respiratory (IFV-RSV) Panel Test, the Idylla™ Instrument and the Idylla™ Console, which is on-track for submission before year-end 2016.

Financial update

- *Non-dilutive financing:* On 20 July 2016, Biocartis announced that it has attracted EUR 55m of non-dilutive financing consisting of a EUR 40m bank and lease financing facility, as well as a new subordinated loan of EUR 15m. The bank and lease financing facility consists of EUR 15m lease financing and EUR 25m multiple purpose credit lines (credit lines partially guaranteed by the Flemish Government through Gigarant). The lease financing will be used to fund the equipment of a second Idylla™ cartridge manufacturing line that Biocartis ordered end of 2015. Furthermore, the two lines of credit that Biocartis now has at its disposal can be used to fulfil certain future financing needs in, amongst others, working capital.
- *Cash position:* Biocartis' cash position end of Q3 2016 amounted to approximately EUR 67m (unaudited figure).

Post-period events

- *AstraZeneca Comparative Study:* On 11 October 2016, the publication of a comparative study organised by AstraZeneca, a global biopharmaceutical company, was announced where 12 different KRAS mutation detecting technologies, including Next-Generation Sequencing (NGS) and quantitative Polymerase Chain Reaction (PCR), were compared for the detection of KRAS mutations in lung cancer, using blinded samples. Results demonstrated superior levels of sensitivity of the Idylla™ KRAS technology to 10 out of the other 11 compared technologies, while at the same time it outperformed competition in ease-of-use and turnaround time. As such, this study confirmed the best-in-class status for the Idylla™ KRAS technology. A poster of the study can be found on the Biocartis website.
- *U.S. partnership:* On 17 November 2016, Biocartis announced it has granted rights in the U.S. to Thermo Fisher Scientific Inc. to distribute its rapid and fully automated molecular diagnostics Idylla™ platform and its accompanying assays, with a first focus on oncology products. Under the terms of the agreement, Thermo Fisher Scientific will be granted distribution rights for Biocartis' Idylla™ molecular diagnostic assays for its customers in the U.S.. Biocartis will retain the right to sell both its Idylla™ platform and assays via direct sales channels. The fully integrated system will enable U.S. laboratories to perform a broad range of molecular tests. Both parties expect to start commercial roll-out as of mid-2017.
- *Commercial leadership team:* To further strengthen and expand the collaborations with pharmaceutical companies, Ulrik Cordes (currently Chief Commercial Officer since September 2013) will transition into the function of EVP Pharma Collaborations and Companion Diagnostics aimed at amongst others building a strong complementary and companion diagnostic business. Hilde Eylenbosch, who joined Biocartis' Board of Directors in May this year, will take over the position of Chief Commercial Officer as of today. She will remain active on the Board of Directors as an Executive Board member. Prior to joining Biocartis, Hilde held amongst others the roles of Chief Commercial Officer at Alere Inc (a global diagnostic device and service provider) and was President of Alere International reporting to the Chief Operational Officer. Hilde holds a degree as Medical Doctor (University of Ghent, Belgium) and successfully completed the General Management Program at Harvard Business School. The commercial experience of Hilde within the global diagnostics markets will be of high value in the continued global roll-out of the Idylla™ platform.

[2] European Society for Medical Oncology. Source: E. Van Cutsem et al, 'ESMO consensus guidelines for the management of patients with metastatic colorectal cancer', Annals of Oncology, published July 5, 2016.
[3] RUO = Research Use Only
[4] 510k clearance is a requirement by the FDA before a product is allowed on the U.S. market. It requires a number of technical or clinical studies.

Commenting on the changes in the commercial leadership team, Hilde Windels, Deputy Chief Executive Officer of Biocartis, said: *"We are very pleased that Hilde Eylenbosch is joining us in an executive role. During her board mandate, she has increasingly been thrilled by the power of our Idylla™ solution and the acceptance in the market by our customers. She will add significant experience to the team and as such will strengthen our capabilities to generate further commercial traction in our current markets. At the same time and in light of more and more traction with current and potential pharma partners, Ulrik will now be in the position to focus on realising the commercial potential of these collaborations as well as to accelerate our efforts in the field of companion diagnostics."*

Outlook

- *Installed base:* Installed base expansion for 2016 is set at the top end of the guided 150-175 range, bringing the expected total installed base to around 340 Idylla™ instruments by year end.
- *Test launch:* Launch of the Idylla™ ctKRAS Mutation Assay (RUO) before the end of the year.
- *Regulatory events:* The following regulatory events for existing Idylla™ tests are expected before the end of the year 2016:
  - CE-marking of the Idylla™ NRAS-BRAF Mutation Test for solid biopsy; and
  - U.S. FDA 510k submissions for the Idylla™ Respiratory (IFV-RSV) Panel Test and the Idylla™ Instrument and Idylla™ Console.
- *Cash position:* Guidance on target cash position by end 2016 in the range of EUR 50m, in line with previously guided range.
- *Idylla™ menu update:* Biocartis will host a Capital Markets Day tailored for institutional investors, research analysts and sector journalists on 2 March 2017 to provide amongst others an update on the future Idylla™ menu alongside the publication of its 2016 full year results.

Financial calendar

- Full year results 2016: 2 March 2017
- Capital Markets Day: 2 March 2017
- Publication annual report 2016: 30 March 2017
- Annual General Meeting: 12 May 2017

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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 launched the Idylla™ platform 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 has five oncology tests and two infectious disease tests on the market. More information: www.biocartis.com. Press Photo Library available here. Follow us on Twitter: @Biocartis_.

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