



## PRESS RELEASE

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## REGULATED INFORMATION

# BIOCARTIS Q1 2017 BUSINESS UPDATE

**Mechelen, Belgium, 27 April 2017** – 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 2017, selected post period events and an outlook for the remainder of the year.

### Key messages

- **Commercial:** Commercial cartridge volume Q1 2017 over 4.5 times Q1 2016 volume. 2017 guidance reiterated: installed base to grow with 250-275 Idylla™ instruments and 2017 annual commercial cartridge volume to be at least three times 2016 volume.
- **Menu:** Continued progress made in expansion oncology menu; CE-marking EGFR solid biopsy test (lung cancer menu) expected in Q2 2017.

**Commenting on the business update, Hilde Windels, interim Chief Executive Officer of Biocartis, said:** “During the first quarter of 2017, we advanced the worldwide adoption of our Idylla™ platform. The strong ramp-up of commercial cartridge volumes that we showed in 2016 was continued in Q1 2017, both in Europe and in our distribution markets. Preparations are ongoing to start US commercialization in the second half of this year and I am pleased about our recent announcement of the appointment of Vishal Sikri as our General Manager for the US.”

### Commercial and regulatory update

- *Cartridge consumption* – Driven by the ongoing installed base growth and menu expansion, Biocartis’ commercial Idylla™ cartridge consumption in Q1 2017 increased to over 4.5 times the Q1 2016 volume.
- *Installed base* – Idylla™ installed base expansion was further continued in Q1 2017, on track to meet guidance of increasing the installed base to over 640 instruments by year end.
- *CDx business* – In January 2017, Biocartis launched its companion diagnostics (CDx) business with the signing of the first CDx partnership with an undisclosed pharmaceutical company (ranked amongst the global top 10 pharmaceutical companies in terms of sales) for the joint development of an Idylla™ CDx test for an undisclosed phase II oncology compound.
- *Commercial footprint* – During Q1 2017, Biocartis obtained new market authorizations in Asia and the Middle East. Furthermore, Biocartis initiated the training of the sales force of Fisher Healthcare (a division of Thermo Fisher Scientific) on the Idylla™ platform as part of Biocartis’ execution plan to start US commercialization in H2 2017.
- *Regulatory* - On 14 March 2017, the US FDA published<sup>1</sup> a preliminary list of devices it plans to exempt from 510(k) premarket notification requirements, subject to certain limitations such as point of care testing. This preliminary list includes real-time PCR devices such as the Idylla™ Instrument and Console. Following a public comment period, a final list is expected to be published and implemented by early July 2017 and could lower the regulatory requirements for the Idylla™ platform<sup>2</sup> in the US.

### Menu update

- *Lung cancer menu* – During Q1 2017, Biocartis completed the clinical validation testing of the Idylla™ EGFR Mutation Assay (RUO<sup>3</sup>) and is on track to CE-mark this assay in Q2 2017. Lung cancer is the most common cancer worldwide, accounting for 13% of all cancer types<sup>4</sup>. Having a CE-marked test for this type of cancer will be an important driver for the further market adoption of the Idylla™ platform. Biocartis aims to launch

<sup>1</sup> Available on <https://www.federalregister.gov/documents/2017/03/14/2017-04938/medical-devices-exemptions-from-premarket-notification-class-ii-devices-request-for-comments>.

<sup>2</sup> Note: this exemption does not hold for assays that are run on the Idylla™ platform.

<sup>3</sup> Research Use Only, not for use in diagnostic procedures.

<sup>4</sup> Navani et al. Lancet Respir Med (2015).

later in 2017 the ctEGFR Mutation Assay, a liquid biopsy RUO version of the Idylla™ EGFR Mutation Assay.

- *Colorectal cancer menu* - On 2 March 2017, Biocartis further expanded its colorectal cancer offering with the launch of the Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay (RUO). This assay launch also marked an important milestone in the partnership with the leading science and technology company Merck KGaA<sup>5</sup>. Biocartis' offering for colorectal cancer now consists of two CE-marked solid biopsy tests (together detecting 44 mutations directly from a slice of FFPE<sup>6</sup> tumor tissue each) and two liquid biopsy assays<sup>7</sup> (available for research use only, together detecting 46 mutations directly from 1 ml of blood plasma each). Furthermore, during Q1 2017 two additional papers were published on the Idylla™ KRAS Mutation Test, reiterating that this test enables fast and reliable analysis of KRAS mutations, without the need for experienced laboratory infrastructure or expertise. One study confirmed that KRAS testing by Idylla™ as such can be carried out in the same center where the patient is diagnosed, which in return allows for a rapid outcome, needed to adequately guide personalized treatment<sup>8</sup>. The other study demonstrated successful testing of cytological samples<sup>9</sup> with Idylla™ which is normally outsourced to a small number of specialized referral molecular pathology laboratories.
- *Melanoma menu* – On 9 March 2017, Biocartis announced the publication in the renowned clinical oncology journal 'The Lancet Oncology' of an important study<sup>10</sup> by Prof. Dr. Bart Neyns from the University Hospital in Brussels (Belgium). In this study, advanced metastatic melanoma patients that had become resistant to their BRAF-targeted treatment were successfully given a retreatment with that same therapy following a three months pause after resistance confirmation. This is an important finding that could lead to more routine use of retreatment, especially for patients where no effective standard treatment is available. Biocartis' liquid biopsy test, the Idylla™ ctBRAF Mutation Assay (RUO), was used in this study for the monitoring of the mutational status.

### **Financial update**

- *MSI grant* - In March 2017, Biocartis received a grant from VLAIO, the Flanders organization for Innovation & Entrepreneurship, of approximately EUR 750k. The grant supports Biocartis' ongoing microsatellite instability (MSI) and mutational load research program in collaboration with Prof. Diether Lambrechts (VIB – KU Leuven Center for Cancer Biology, Belgium), and aims to support the development of a fully automated MSI test on the Company's Idylla™ platform aimed at colorectal cancer and immunotherapies for oncology.
- *Cash position* - Biocartis' cash position end of Q1 2017 amounted to approximately EUR 70m (unaudited figure). The Company has EUR 25m of multiple purpose credit lines at its disposal on which no drawdowns were made as per end of March 2017. Biocartis targets a cash position by the end of 2017 of around EUR 40m.

### **Post-period events**

On 4 April 2017, Biocartis announced the establishment of its US subsidiary, Biocartis US Inc., and the appointment of Vishal Sikri as its US General Manager. Vishal is a highly experienced executive with a proven global commercial and operational track-record in molecular diagnostics. Before joining Biocartis, he was Managing Director and VP Commercial Operations responsible for all global commercial operations of Sysmex Inostics, the molecular diagnostics' division of Sysmex Corporation (TYO: 6869).

### **Menu outlook 2017**

- CE-marking Idylla™ EGFR Mutation Test (Q2 2017).
- CE-marking Idylla™ NRAS Mutation Test (Q2 2017): this test will give more flexibility to customers and will allow for price differentiation with the Idylla™ NRAS-BRAF Mutation Test in geographies where BRAF testing for mCRC patients is not reimbursed.
- CE-marking Idylla™ ctKRAS Mutation Test and Idylla™ ctNRAS-BRAF Mutation Test as part of the partnership with Merck (H2 2017).

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<sup>5</sup> Darmstadt, Germany.

<sup>6</sup> Formalin-fixed paraffin embedded.

<sup>7</sup> The Idylla™ KRAS Mutation Test and the Idylla™ NRAS-BRAF Mutation Test are CE-marked IVD tests which can be used in diagnostic procedures. The Idylla™ ctKRAS Mutation Assay and the Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay are Research Use Only (RUO) and not for use in diagnostic procedures.

<sup>8</sup> Weyn et al., 'Clinical performance evaluation of a sensitive, rapid low-throughput test for KRAS mutation analysis using formalin-fixed, paraffin-embedded tissue samples', BMC Cancer, published online 16 February 2017.

<sup>9</sup> De Luca et al., 'KRAS detection on archival cytological smears by the novel fully automated polymerase chain reaction-based Idylla™ mutation test', CytoJournal, published on 24 February 2017. Cytology or cytopathology means diagnosing diseases by looking at single cells and small clusters of cells. It is an important part of diagnosing some types of cancer. Source: [www.cancer.org](http://www.cancer.org), last consulted on 12 April 2017.

<sup>10</sup> Schreuer et al., 'Combination of dabrafenib plus trametinib for BRAF and MEK inhibitor pretreated patients with advanced BRAFV600-mutant melanoma: an open-label, single arm, dual-centre, phase 2 clinical trial', The Lancet Oncology 2017, published online 3 March 2017.

- Launch of a liquid biopsy version of the Idylla™ EGFR Mutation Assay (RUO, H2 2017). Note: this product will be initially launched on the basis of a manual DNA extraction protocol anticipating a fully automated ctEGFR Mutation Assay (RUO) that is also under development.
- 510(k) approval from the US FDA is expected for the Idylla™ Instrument, the Idylla™ Console and the Idylla™ Respiratory (IFV-RSV) Panel.

### **Financial calendar 2017**

- Annual General Meeting Biocartis Group NV - 12 May 2017
- H1 2017 results – 7 September 2017
- Q3 2017 business update – 16 November 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 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 eight oncology tests and two infectious disease tests in its product menu. More information: [www.biocartis.com](http://www.biocartis.com). Press Photo Library available [here](#). Follow us on [Twitter](#): @Biocartis\_.

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