PRESS RELEASE REGULATED INFORMATION

BIOCARTIS Q1 2016 BUSINESS UPDATE

Mechelen, Belgium, **12 May 2016 -** 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 2016 and outlook for the remainder of the year.

Key messages

- Significantly increased commercial cartridge consumption in Q1 2016 driven by availability as of December 2015 of a full Idylla™ RAS solid biopsy test offering (colon cancer), as well as a BRAF test offering (melanoma) for both solid and liquid biopsies;
- On track to complete critical mass of solid biopsy testing for oncology (comprising four tests) in H1 2016 with the planned launch of a solid biopsy lung cancer panel in Q2 2016; and
- Guidance for 2016 reiterated: launch of at least four new tests, installed base to grow with 150-175 Idylla™ instruments and year-end cash position in the range of EUR 45m to EUR 55m.

Commenting on the business update, Rudi Pauwels, Chief Executive Officer of Biocartis, said:

"*I am excited to see that an increasing number of clients are starting to use Idylla™ based testing in routine use and that liquid biopsy testing also continues to generate a wider interest. Both developments will have a positive impact on patients as they add significant value to cancer treatment.*

Following a successful 2015, our teams are paving the way to execute on the promises that we set for 2016. I am really looking forward to the launch of the fourth Idylla™ solid biopsy test for oncology, our Lung Cancer Panel, in Q2 2016. This will be a first milestone in the completion of our core menu for oncology, something a lot of our prospects are waiting for and as such will further drive installed base growth."

Commercial update

Biocartis is commercialising its molecular diagnostics platform Idylla™ via direct representations in key European countries and via distribution partners in geographies accepting the CE-mark.

- *Cartridge consumption*: The launch in December 2015 of the NRAS-BRAF-EGFR S492R Mutation Assay and the Idylla™ ctBRAF Mutation Assay were instrumental for the ramp up of commercial cartridge consumption in Q1 2016. These tests respectively completed the Idylla™ solid biopsy RAS offering (enabling a 'same day' full RAS analysis) and allowed clients to test for BRAF mutations on both solid and liquid samples on the same platform. The latter meets the demand from clients that have interest in BRAF testing on both types of samples simultaneously. The Idylla™ KRAS Mutation Test was the top selling product in Q1 2016.
- *Installed base:* Installed base growth was further progressed in Q1 2016 and is on track to realise the target of adding 150-175 Idylla™ instruments in 2016, driven by the additional tests that Biocartis envisages to launch before year end.
- *Commercial footprint:* Expansion of Biocartis' global commercial footprint was continued in Q1 2016 with the addition of five direct sales representatives and the signing of new distribution agreements in Asia.

Idylla™ test menu update

During Q1 2016, Biocartis further advanced the development of new tests for its Idylla™ platform with a focus on its core menu for oncology (e.g. solid and liquid biopsy tests for melanoma, colon and lung cancer) and the first wave of infectious disease tests. Biocartis reiterates its guidance to launch at least four new tests in 2016.

Oncology menu

- *Solid biopsies:* In Q2 2016, Biocartis aims to launch its fourth solid biopsy test for oncology, which will allow for state-of-the-art testing in lung cancer, the largest indication in oncology. The Idylla™ Lung Cancer Panel is

expected to analyse over 50 genetic changes in one of the key lung cancer driver genes, from just a single slice of FFPE[1] in approx. 2.5 hours. Compared to existing tests, this is a significant reduction in the number of required samples and turnaround time. Due to its unique features, the test is expected to attract interest from both laboratories that do not dispose of molecular diagnostics infrastructure, as well as large reference centres. The exact panel composition will be disclosed upon launch of the test.

- *Liquid biopsies:* Following the announcement in January 2016 of the collaboration with Merck KGaA for the development and commercialisation of a new liquid biopsy RAS biomarker test for patients with metastatic colorectal cancer (mCRC), Biocartis accelerated in Q1 2016 the development of liquid biopsy versions of the Idylla™ KRAS Mutation Test and the Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay. Both assays are expected to be launched in the second half of 2016. Upon launch, Idylla™ is expected to be the only platform that can offer sample to result extended RAS testing, for both solid and liquid biopsies, on the same system.
- *Extended test applicability:* Idylla™ oncology tests are validated for specific cancer and sample types. In Q1 2016, numerous academic centres that use Idylla™ studied the applicability of our tests for additional cancer and/or sample types. For example, the Idylla™ BRAF Mutation Test was successfully tested on colon and thyroid cancer samples, and the Idylla™ KRAS Mutation Test on pancreas and lung cancer samples. Additional samples types successfully tested by these centres included low amounts of extracted DNA, cytological samples and fine-needle aspirates (FNA). The excellent results shown during these studies could be used to extend the clinical applicability of the respective tests, thereby increasing their overall market potential.

Infectious disease menu

Biocartis' initial focus within infectious diseases is on offering highly sensitive syndromic panel tests, tests that complement Biocartis' disease surveillance strategy and tests for fast monitoring of bloodstream infections (including Sepsis).

- *Respiratory menu:* Following CE-marking of the Idylla™ Respiratory (IFV-RSV) Panel in Q4 2015, Biocartis initiated, together with Janssen Diagnostics US clinical studies for this test in Q1 2016 (to pursue US Food and Drug Administration (FDA) 510k[2] clearance). Furthermore, Biocartis continued to be on track with the development of its second and third respiratory test, being respectively the MERS Test and the Respiratory Mixed Panel Test that is capable of detecting over 25 different viral and bacterial pathogens.
- *Ebola test:* In Q1 2016, Biocartis completed the interactive review process with the US FDA for its Idylla™ Rapid Ebola Virus Triage Test and is now awaiting 'Emergency Use Authorisation' (EUA).
- *Bloodstream infections (including Sepsis):* Workflow automation design improvements have been completed in Q1 2016 for the Idylla™ Bloodstream Infections (BSI) Test. Biocartis' expert meeting in March 2016 with international key opinion leaders once more confirmed that the Idylla™ BSI Test's comprehensive panel and rapid turnaround time is expected to enable a more appropriate antibiotic stewardship, and that the new highly automated workflow will make it suitable for usage in intensive care units as well as in emergency rooms.

Financial and organisational update

- *Cash position:* Biocartis' cash position end of Q1 2016 amounted to approx. EUR 84m. The cash burn for Q1 2016 was impacted by the pre-financing of over EUR 5m of investments for cartridge manufacturing expansion. Biocartis is currently having discussions to refinance these investments with a new financing facility. Guidance on the cash position for the end of 2016 in the range of EUR 45m to EUR 55m is reiterated.
- *Executive team:* During Q1 2016, Biocartis strengthened its manufacturing expertise with the appointment of Reginald Van Genechten (Head of Manufacturing and Supply Chain) who will also be a member of the executive management team. Before joining Biocartis, Reginald held positions as, amongst others, Head of Technical Operational Excellence at McNeil (US based) and Senior Director Johnson&Johnson Global Supply Chain. Furthermore, Patrick Hofkens (General Counsel) decided to take up another professional challenge outside Biocartis.
- *Board of Directors:* Biocartis recommends the Annual General Meeting to appoint Hilde Eylenbosch as a new non-executive member of its Board of Directors. Hilde is a Senior Business Executive with over 25 years of experience in marketing, product innovation, cross functional businesses and organisational leadership in the life sciences industry. Over the last five years, she held 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. The commercial experience of Hilde in the global diagnostics industry will further assist

[1] Formalin-fixed paraffin embedded samples are samples, typically from suspected tumours, that are fixed or mixed with formalin to preserve the structural integrity of the sample. The sample is then embedded into a type of paraffin wax so that it can be sliced into very fine slices, 5-10 microns thick.

[2] 510k clearance is a requirement by the FDA before a product is allowed on the US market. It requires a number of technical or clinical studies.

Biocartis in successfully commercialising its Idylla™ platform and tests.

Expected news flow remainder 2016

- The following test launches are expected:
  - Solid biopsy Lung Cancer Panel (Research Use Only, Q2 2016);
  - Idylla™ Rapid Ebola Virus Triage Test (Based on US FDA 'Emergency Use Authorisation', Q2 2016);
  - Two liquid biopsy tests for colon cancer, being liquid biopsy versions of the Idylla™ KRAS Mutation Test and the Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay (Research Use Only, H2 2016); and
  - Idylla™ MERS Test (Middle East Respiratory Syndrome, H2 2016).
- The following regulatory updates of existing Idylla™ tests are expected:
  - CE-marking of the Idylla™ NRAS and NRAS/BRAF solid biopsy tests (H2 2016); and
  - US FDA 510k submission for the Idylla™ Respiratory (IFV-RSV) Panel and the Idylla™ Instrument and Idylla™ Console.

Financial calendar 2016

- Annual General Meeting Biocartis Group: 13 May 2016
- Half year results H1 2016: 6 September 2016
- Q3 Business Update 2016: 17 November 2016

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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 four oncology tests and one test for infectious diseases on the market. More information: www.biocartis.com. Follow us at @Biocartis .