PRESS RELEASE

REGULATED INFORMATION
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BIOCARTIS ANNOUNCES H1 2017 RESULTS

Mechelen, Belgium, **7 September 2017 –** Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces its business highlights and financial results for the first half of 2017, prepared in accordance with the IAS 34 Interim Financial Reporting as adopted by the European Union. Furthermore, the Company provides it latest outlook for 2017.

Key messages

- **Commercial product revenues:** Commercial product revenues in H1 2017 showed a year-over-year growth of 195% and amounted to EUR 5.0m (EUR 1.7m in H1 2016). Total operating income amounted to EUR 7.0m in H1 2017.
- **Cartridge consumption:** Increased to approximately 27k cartridges in H1 2017, being 110% of the volume for the full year 2016.
- **Installed base:** Increased with 108 Idylla™ instruments in H1 2017, bringing the total to 497 as per 30 June 2017.
- **Menu of tests:** Further strengthened in H1 2017 with two new CE-markings (Idylla™ EGFR Mutation Test and Idylla™ NRAS Mutation Test), launch of the third liquid biopsy assay (Idylla™ ctNRAS-BRAF-EGFR-S492R Mutation Assay, RUO[1]) and strong progress in new test development through amongst others new partnerships in the breast cancer domain.
- **Cash position:** Cash and cash equivalents of EUR 59.0m as per end H1 2017. In addition, the Company has EUR 25m of multiple purpose credit lines at its disposal on which no drawdowns were made as per end of H1 2017.
- **Guidance:** 2017 guidance on cartridge consumption (at least three times 2016 volume), installed base growth (250-275 new instrument placements) and year-end cash position (around EUR 40m) reiterated.

Biocartis will host a conference call with live webcast presentation today at 14:00 CEST / 13:00 BST (UK) / 08:00 EDT (US) to discuss the H1 2017 results. Click here to access the live webcast.

To participate in the questions and answers session, please dial 5-10 minutes prior to the start time the number +44(0)20 3427 1902 (standard international), followed by the confirmation code 4254599.

The conference call and webcast will be conducted in English.
A replay of the webcast will be available on the Biocartis investors' website shortly after.

Commercial highlights

- *Cartridge consumption:* Strong continued ramp-up of commercial Idylla™ cartridge consumption in H1 2017 driven by menu expansion and installed base growth. H1 2017 commercial volume increased to approximately 27k cartridges, being 110% of the total volume for the full year 2016. Cartridges for colorectal cancer (CRC) testing represented the majority of the volume in H1 2017.
- *Installed base:* A total of 108 Idylla™ instruments where added to the installed base in H1 2017, resulting in a total installed base of 497 instruments as per end of June 2017. H1 2017 showed strong placements in both the European and RoW[2] markets.
- *Commercial footprint*: During H1 2017, Biocartis established its US subsidiary, recruited its core US team and initiated the training of the sales force of Fisher Healthcare (a division of Thermo Fisher Scientific Inc.) aimed at starting US commercialization of the Idylla™ platform in H2 2017. Furthermore, Biocartis signed additional distribution agreements in Asia and Latin America and added product registrations in Asia, the Middle East and Latin America.
- *CDx business*: In January 2017, Biocartis signed its first companion diagnostic ('CDx') partnership with an

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

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. The CDx partnership between Abbott Molecular and Biocartis expired in H1 2017.

Test menu highlights

As per end H1 2017, Biocartis' oncology menu consisted of 10 Idylla™ tests of which six for colorectal cancer, two for lung cancer and two for melanoma testing.

- *Colorectal cancer menu* – In H1 2017, Biocartis expanded its CRC menu with the launch of the Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay (RUO) and the CE-marking of Idylla™ NRAS Mutation Test. The Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay is the third liquid biopsy test of Biocartis and marked an important milestone in the partnership with the leading science and technology company Merck[3]. The solid biopsy Idylla™ NRAS Mutation Test, alongside Biocartis' existing Idylla™ NRAS-BRAF Mutation Test, will allow for more flexibility in geographies where BRAF testing for metastatic CRC patients is not reimbursed.
- *Lung cancer* – In June 2017, Biocartis CE-marked its solid biopsy Idylla™ EGFR Mutation Test, which is an important addition to Biocartis' oncology menu. This test is the only on-market fully automated CE-IVD test detecting all relevant EGFR mutations according to international guidelines and is able to produce results faster and easier[4], based on only one slice of tumor tissue. Furthermore, in H1 2017, Biocartis advanced the development of a liquid biopsy version of the Idylla™ EGFR Test aimed for launch later this year. This test, now able to operate directly from plasma, will further strengthen Biocartis' lung cancer menu as tumor tissue in lung cancer is often not available and it allows for patient monitoring.
- *Melanoma menu* – In March 2017, a study[5] by Prof. Dr. Bart Neyns from the University Hospital in Brussels (Belgium) was published in the renowned clinical oncology journal The Lancet Oncology. This study showed that advanced metastatic melanoma cancer patients that had become resistant to their BRAF-targeted treatment[6] 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 alternative 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.
- *Breast cancer menu* – In June 2017, Biocartis initiated the development of the first test for its breast cancer menu aimed at monitoring of metastatic breast cancer patients for resistance to hormone therapy. Breast cancer is the most common cancer among women worldwide: one in eight women is diagnosed with breast cancer in her lifetime[7]. This test will be jointly developed under a new partnership with LifeArc (formerly MRC Technology), focused on developing selected molecular diagnostic tests for use on the Idylla™ platform.
- *MSI testing* – In March 2017, Biocartis received a grant of approx. EUR 750k from VLAIO, the Flanders organization for Innovation & Entrepreneurship, for the further development of a fully automated microsatellite instability (MSI) test on the Idylla™ platform. The MSI test that Biocartis has under development and aims to launch in 2018, could be validated as a prognostic test for CRC and a predictive test for cancer immunotherapies, the latter being a fast growing market, expected to be worth over USD 100bn by 2021[8].

Organizational highlights

- *Change in CEO position* – In March 2017, Biocartis announced a change in the CEO position as Rudi Pauwels took on the role of Chairman of a new Strategy Committee of the Board and Hilde Windels assumed the role of interim CEO. On 10 May 2017, Biocartis announced its new CEO Herman Verrelst, who started 1 September 2017. Herman is a seasoned executive with a proven international commercial track-record in molecular diagnostics and held the position of Vice President and General Manager of the Genomics and Clinical Applications Division of Agilent Technologies Inc. (NYSE: A) prior to joining Biocartis. Hilde Windels will continue to support the company as Executive Director within the Biocartis Board of Directors.
- *US General Manager* – In April 2017, Biocartis announced the appointment of Vishal Sikri as its US General Manager. Before joining Biocartis, Vishal 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).
- *Galenus Prize* – In May 2017, Biocartis won the prestigious 2016 Galenus Prize for the Most Innovative Medical

[3] Merck KGaA, Darmstadt, Germany.
[4] Based on a comparison between the Biocartis' Idylla™ platform for the detection of EGFR mutations in archived formalin-fixed paraffin-embedded (FFPE) tumor samples with the results obtained by the TherascreenEGFR Pyro assay (Qiagen)-ISO 15189 accredited laboratory method.
[5] 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.
[6] It concerns treatments with dabrafenib and/or trametinib (Tafinlar™ and Mekinist™, both products marketed by Novartis)
[7] Source: World Cancer Research Fund International, http://www.wcrf.org/int/cancer-facts-figures/data-specific-cancers/breast-cancer-statistics, last consulted on 17 May 2017.
[8] Source: Cancer Immunotherapy Market by Type (Monoclonal Antibodies, Cancer Vaccines, Check Point Inhibitors & Immunomodulators), Application (Lung, Breast, Colorectal, Melanoma, Prostate, Head & Neck), End User (Hospital and Clinics) - Global Forecast to 2021, published by MarketsandMarkets.

Device, leading the way to better treatments, with its fully automated Idylla™ NRAS-BRAF Mutation Test for CRC patients.

Financial highlights

- *Product sales revenues* – Product sales revenues showed a year-over-year growth of 88% and amounted to EUR 5.1m in H1 2017. During the same period, cartridge sales grew year-over year with 90% to EUR 3.3m and Idylla™ system sales with 84% to EUR 1.8m. Total commercial product sales amounted in H1 2017 to EUR 5.0m, representing a year-over-year growth of 195% that was mainly driven by the increased commercial cartridge consumption.
- *Operational expenses* - Total operating expenses (including cost of sales), amounted to EUR 30.7m in H1 2017 versus EUR 30.8m in H1 2016. Operating expenses excluding costs of goods in H1 2017 amounted to EUR 27.4m versus EUR 28.8m in H1 2016, a decrease of approx. 5% predominantly due to lower expenses for research and development.
- *Net cash flow* - Total net cash flow in H1 2017 amounted to EUR -24.2m versus EUR -28.3m in H1 2016, a year-over-year improvement of 15%.
- *Cash position* - Biocartis' cash position as per end June 2017 amounted to EUR 59.0m compared to EUR 83.2m as per 31 December 2016. In addition, the Company has EUR 25m of multiple purpose credit lines at its disposal on which no drawdowns were made as per end of H1 2017.
- *Additional details* – See 'key figures for H1 2017' below for more details on the H1 2017 financials.

Commenting on the H1 2017 results, Hilde Windels, interim Chief Executive Officer Biocartis (until 31 August 2017), said: "*Our H1 2017 performance is best characterized by the 195% growth that we realized year-over-year in commercial product revenues. This shows that our investments in menu and geographical expansion successfully translated into higher commercial volumes, demonstrating the adoption of the Idylla™ platform in our current markets. We are thrilled to start selling in the US market in the second half of this year and look forward to important tests launches in the coming months. This will put us in an excellent position to continue this impressive growth curve. I am confident that under the leadership of Herman Verrelst, our new CEO as of 1 September, Biocartis will also continue to deliver on its promises to globally impact the way molecular diagnostics is performed*."

Post-period events

- *Breast cancer menu* – In July 2017, Biocartis and ETPL (the commercialization arm of A*STAR, Singapore's Agency for Science, Technology and Research) initiated the development of second test for the Idylla™ breast cancer menu: a fully automated solid biopsy assay, aimed at supporting optimal therapy selection decisions for breast cancer patients. This development is part of a renewed five-year strategic partnership with ETPL[9], focused on the development of molecular diagnostic assays for Biocartis' Idylla™ platform. The partnerships with ETPL and LifeArc fit well with Biocartis' strategy to accelerate the expansion of its menu of molecular diagnostic tests through third party partnerships.
- *510(k) exemption Idylla™ instrumentation* – In July 2017, the US FDA[10] published a final list of devices that it has exempted from 510(k) premarket notification requirements. The product codes applicable to the Biocartis Idylla™ Instrument and Idylla™ Console are included on this list. The exemption of the Biocartis Idylla™ Instrument and Idylla™ Console is expected to accelerate the introduction of the Idylla™ platform in the US.
- *MSI performance data* – On 31 August 2017, Biocartis announced the publication of two study abstracts, selected for presentation at the ESMO congress in September 2017, regarding the performance of its exclusively licensed novel set of biomarkers for microsatellite instability (MSI) that are to be included in the Idylla™ MSI Test (the 'MSI Biomarkers'). Both studies (of which one conducted in collaboration with Merck KGaA, Darmstadt, Germany) showed superior performance of the MSI Biomarkers compared to the reference methods.
- *US FDA 510(k) clearance Idylla™ Respiratory (IFV-RSV) Panel* – On 5 September 2017, Biocartis announced that the US Food and Drug Administration (FDA) has granted 510(k) clearance[11] for the Idylla™ Respiratory (IFV-RSV) Panel.

[9] On 17 July 2015, Biocartis signed a partnership agreement with ETPL, the commercialization arm of the Agency for Science, Technology and Research (A*STAR, based in Singapore). A*STAR is Singapore's lead public sector agency that spearheads economic oriented research to advance scientific discovery and develop innovative technologies. Under the partnership, Biocartis had access to novel biomarkers (including those discovered within A*STAR's research institutes) from the Diagnostics Development Hub under ETPL.
[10] US Food and Drug Administration.
[11] Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance. This is known as Premarket Notification - also called PMN or 510(k).

Outlook 2017

- Guidance for 2017 full year reiterated:
  - Grow the total installed base to 640 Idylla™ instruments by adding 250-275 new instrument placements;
  - Grow commercial cartridge consumption to over three times the 2016 volume; and
  - Realize a cash position by the end of 2017 of around EUR 40m.
- Expected test menu news flow in H2 2017:
  - CE-marking Idylla™ ctKRAS Mutation Test and Idylla™ ctNRAS-BRAF Mutation Test as part of the partnership with Merck[12]; and
  - Launch of a liquid biopsy version of the Idylla™ ctEGFR Mutation Assay (RUO).

Key figures for H1 2017

The tables below show an overview of the key figures and a breakdown of operating income for H1 2017. Consolidated financial statements including notes are included in Biocartis' financial report for H1 2017 that can be downloaded from the Company's website here.

Key figures *(EUR 1,000)*	H1 2017	H1 2016	% Change
Total operating income	**6,978**	**6,750**	**3%**
Cost of sales	-3,278	-1,921	71%
Research and development expenses	-19,320	-20,699	-7%
Marketing and distribution expenses	-5,308	-5,259	1%
General and administrative expenses	-2,781	-2,874	-3%
Operating expenses	**-30,687**	**-30,754**	**0%**
Operational result	**-23,709**	**-24,003**	**-1%**
Net financial result	-729	-282	159%
Income tax	456	501	-9%
Net result	**-23,982**	**-23,784**	**1%**
Cash flow from operating activities	-22,172	-25,345	-13%
Cash flow from investing activities	-1,531	-6,912	-78%
Cash flow from financing activities	-479	3,919	-112%
Net cash flow	**-24,182**	**-28,338**	**-15%**
Cash and cash equivalents[1]	**59,042**	**75,757**	**-22%**
Financial debt	33,279	16,544	6%

[1] Including EUR 1.2m of restricted cash (as a guarantee for KBC lease financing)

Operating income *(EUR 1,000)*	H1 2017	H1 2016	% Change
Collaboration revenue	716	3,377	-79%
Idylla™ System sales	1,821	988	84%
Idylla™ Cartridge sales	3,270	1,723	90%
Product sales revenue	5,092	2,711	88%
Service revenue	104	20	411%
Total revenue	**5,912**	**6,109**	**-3%**
Grants and other income	1,066	641	66%
Total operating income	**6,978**	**6,750**	**3%**

[12] Merck KGaA, Darmstadt, Germany.

Product sales revenue (EUR 1,000)	H1 2017	H1 2016	% Change
Commercial revenue	5,024	1,705	195%
Research & Development revenue	67	1,006	-93%
Total product sales revenue	**5,092**	**2,711**	**88%**

Income statement
Collaboration revenues in H1 2017 decreased year-over-year with approx. 79% to EUR 0.7m primarily driven by significantly lower recognized upfront license revenues from strategic partners: EUR 3.3m in H1 2016 versus EUR 0.7m in H1 2017. Product sales revenue on the other hand increased year-over-year with approx. 88% in H1 2017 to EUR 5.1m driven by higher revenues from commercial activities. Furthermore, grant and other income increased year-over year with approx. 66% to EUR 1.1m due to higher R&D project support grants and training subsidies related to the establishment of a second cartridge manufacturing line. Total operating income consequently amounted to EUR 7.0m in H1 2017 versus EUR 6.8m in H1 2016, representing an increase of 3%.

Total operating expenses in H1 2017 remained with EUR 30.7m more or less on the same level of H1 2016 (EUR 30.8m) due to an increase in costs of sales that was offset by lower expenses for R&D and G&A. Costs of sales increased in H1 2017 to EUR 3.2m (71% year-over-year growth) due to higher commercial cartridge and instrumentation volumes.

Expenses for R&D decreased year-over-year with approx. 7% to EUR 19.3m in H1 2017. This was predominantly driven by lower staff and subcontracting costs, partially offset by higher Idylla™ platform and cartridge prototype costs and increased consultancy expenses. Expenses for Marketing & Distribution remained year-over-year on the same level and amounted to EUR 5.3m in H1 2017 as higher costs for staff, facilities and TT&C (Travel, Training and Conferences) were offset by lower subcontracting and sales & promotional expenses. G&A expenses decreased year-over-year with 3% to EUR 2.8m as the consequence of lower staff and TT&C costs that were only partially offset by higher costs for human resources and external advice. Overall, operational expenses excluding costs of sales amounted to EUR 27.4m in H1 2017, representing a year-over-year decrease of approximately 5%.

The above resulted in an operational result for H1 2017 equal to EUR –23.7m compared to EUR -24.0m in H1 2016. Following a net financial result for H1 2017 of EUR –0.7m and positive income taxes of EUR 0.5m, the net result for H1 2017 equaled to EUR –24.0m compared to EUR -23.8m for the same period in 2016.

Balance sheet
Property, plant and equipment increased in H1 2017 to EUR 24.3m from EUR 23.1m at the end of 2016 (increase of EUR 1.2m) driven by capital expenditures in H1 2017 of EUR 3.3m (predominantly related to investments for cartridge manufacturing expansion) and a depreciation charge of around EUR 2.0m. Inventory slightly increased to EUR 9.9m (year-over-year increase of 1%) as higher stock of finished products (predominantly Idylla™ cartridges) were nearly fully offset by lower levels of raw materials and semi-finished products driven by ongoing supply chain efficiency initiatives. An increase in trade and other receivables of approx. EUR 0.1m in H1 2017 was offset by an increase in trade payables with a comparable amount. Other current assets increased year-over-year with approx. 22% to EUR 2.4m in H1 2017 as the consequence of higher accrued grant income.

The Company's cash and cash equivalents end of H1 2017 amounted to EUR 59.0m compared to EUR 83.2m end of 2016. Total financial debt end of H1 2017 amounted to EUR 33.3m, representing an increase of approx. EUR 1.9m compared to end of 2016. This was the result of an increase in lease financing in the context of the ongoing cartridge manufacturing expansion, as well as the addition of capitalized interest to the Company's subordinated loan.

Cash flow statement
The cash flow from operating activities in H1 2017 amounted to EUR –22.2m compared to EUR -25.3m in H1 2016 (an increase of approx. 13%), primarily because of modest working capital investments in H1 2017 (compared to material investments in working capital and significant movements in deferred income in H1 2016). The cash flow from investing activities in H1 2017 amounted to EUR –1.5m (compared to EUR -6.9m in H1 2016) and is mainly related to capitalized Idylla™ systems placed with customers under (reagent) rental agreements and Idylla™ systems used for internal needs. The EUR 1.8m investments for cartridge manufacturing expansion are excluded from the cash flow from investing activities since these were directly paid via lease financing. The cash flow from

financing activities in H1 2017 amounted to EUR -0.5m (compared to EUR 3.9m in H1 2016) and relates to repayments of borrowings. Because of the aforementioned, the net cash flow of H1 2017 amounted to EUR –24.2m compared to EUR -28.3m in H1 2016, representing an increase of 15% year-over-year.

Financial calendar 2017

- Extraordinary General Meeting Biocartis Group NV – 11 September 2017
- Q3 2017 business update – 16 November 2017
- 2017 full year results – 1 March 2018
- Publication 2017 annual report –5 April 2018

Webcast and presentation

Biocartis will host a conference call with live webcast, during which the H1 2017 results will be presented, followed by a Q&A session. This event will be held today, 7 September 2017 at 14:00 CEST / 13:00 BST (UK) / 08:00 EDT (USA). Access the webcast by clicking here. If you would like to participate in the Q&A, please dial +44(0)20 3427 1902 (standard international), followed by the confirmation code 4254599. A replay of the webcast will be available on the Biocartis investors' website shortly after.

Auditor Statement

The condensed consolidated financial statements for the six-month's period ended 30 June 2017 have been prepared in accordance with IAS 34 'Interim Financial Reporting' as adopted by the European Union. They do not include all the information required for the full annual financial statements and should therefore be read in conjunction with the financial statements for the year ended 31 December 2016. The condensed consolidated financial statements are presented in thousands of Euros (unless stated otherwise). The condensed consolidated financial statements have been approved for issue by the Board of Directors on 31 August 2017. The statutory auditor, Deloitte Bedrijfsrevisoren/Reviseurs d'Entreprises, represented by Gert Vanhees, has performed a limited review, which did not reveal any significant adjustments to the condensed consolidated financial statements. The interim financial report 2017 and the limited review opinion of the auditor are available on www.biocartis.com.

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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 offers ten oncology tests and two infectious disease tests in Europe. More information: www.biocartis.com. Press Photo Library available here. Follow us on Twitter: @Biocartis_.

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. 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.