PRESS RELEASE REGULATED INFORMATION

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BIOCARTIS ANNOUNCES H1 2016 RESULTS

Mechelen, Belgium, **6 September 2016 –** Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces its operational highlights and financial results for the first half of 2016, prepared in accordance with the IAS 34 Interim Financial Reporting as adopted by the European Union. Furthermore, the Company provides an updated outlook for 2016.

KEY MESSAGES

- **General:** H1 2016 demonstrates an initial validation of Biocartis' razor-razorblade business model as the increased installed base of Idylla™ instruments and broadened menu of Idylla™ tests are resulting in an accelerated growth of cartridge consumption.

- **Cartridge volume:** Commercial cartridge volume in H1 2016 was more than twice the volume for the full year 2015 number.

- **Installed base:** A total of 106 Idylla™ instruments were added to the installed base in H1 2016, bringing the total to over 270 as per 30 June 2016. Guidance on instrument placements for 2016 is now set at the top end of the targeted 150 - 175 range.

- **Menu expansion:** Launch of the Idylla™ EGFR Mutation Assay, a key addition to Biocartis' core menu for oncology and first U.S. FDA achievement with the granting of the Emergency Use Authorisation (EUA) for the Idylla™ Ebola Virus Triage Test. Guidance to launch at least four new tests in 2016 reiterated.

- **Financials:** Product revenues increased to EUR 2.7m in H1 2016 compared to EUR 1.7m in H1 2015, an increase of 63%. Total operating income over the same period decreased with 7% to EUR 6.8m (EUR 7.2m in H1 2015) as no new milestone payments were collected in H1 2016. Cash and cash equivalents on 30 June 2016 amounted to EUR 75.8m. Guidance on end of year cash position in the range of EUR 45m to EUR 55m reiterated.

The Biocartis management team 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 2016 results. The live webcast may be accessed by clicking here.

To participate in the questions and answers session, please dial 5-10 minutes prior to the start time the number +44(0)20 3427 1908 (standard international), followed by the confirmation code 6014209.

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

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

- *Installed base:* A total of 106 Idylla™ instruments were added to the installed base in H1 2016, bringing the total to over 270 instruments as per 30 June 2016. A key driver behind the new installations was the expansion of the oncology menu by end 2015, which doubled from two to four tests with the launch of the Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay and the Idylla™ ctBRAF Mutation Assay. Furthermore, the launch of the Idylla™ EGFR Mutation Assay on 21 June 2016 was another important element behind the installed base growth in H1 2016 as many clients had been waiting for this breakthrough test. Because of the launch timing of the Idylla™ EGFR Mutation Assay, a significant number of the new installations were placed with customers towards the end of Q2 2016.
- *Cartridge consumption:* Following installed base growth and the continued menu expansion, H1 2016 showed a significant pick-up in commercial cartridge consumption and associated product revenues. This demonstrates an initial validation of the 'razor-razorblade' approach that Biocartis follows. The total commercial cartridge volume in H1 2016 was equal to more than two times the volume for the full year 2015. The top selling product in H1 2016 was the Idylla™ KRAS Mutation Test (colorectal cancer), followed by the Idylla™ BRAF Mutation Test (melanoma cancer).

Idylla™ test menu highlights

During H1 2016, Biocartis further advanced the development of new tests for its Idylla™ platform with a focus on completing its core menu for oncology (i.e. tests for melanoma, colon and lung cancer) and launching its second infectious disease test.

Oncology menu

Biocartis currently markets five oncology tests, consisting of four solid biopsy tests and one liquid biopsy test. To date, these tests generate most of the commercial cartridge revenues.

- *Solid biopsy menu*: On 21 June 2016, Biocartis realised another important milestone in completing its core menu for oncology with the launch of a test for lung cancer, the Idylla™ EGFR Mutation Assay (RUO[1]). This advanced, fully automated molecular test is designed to detect over 50 EGFR mutations which commonly occur in lung cancer and demonstrates, amongst others, the high multiplex capabilities of the Idylla™ platform. A CE-IVD version of the Idylla™ EGFR Mutation Assay is planned for 2017. A liquid biopsy version is also under development. Furthermore, in H1 2016 Biocartis continued the additional validation work needed to obtain CE-marking for its Idylla™ NRAS and NRAS/BRAF solid biopsy tests in H2 2016. Once obtained, Biocartis will be able to offer a complete RAS-BRAF analysis for clinical use on a same-day basis. The importance of offering this joint RAS-BRAF analysis was recently underlined with the new ESMO[2] guidelines as described below, which further opens up the route towards faster treatment selection ('same day results').
- *Liquid biopsy menu:* The promising results from liquid biopsies - which enable the identification of tumour mutations in the blood of patients - and concordance studies[3] currently being conducted are expected to further validate the clinical utility of these products. This underlines once more the importance of the various liquid biopsy tests Biocartis has under development. The development of liquid biopsy versions (RUO) of the Idylla™ KRAS Mutation Test and the Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay, as part of the collaboration signed with Merck KGaA in January 2016, is on track for launch in H2 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.
- *Performance of Idylla™ tests:* In H1 2016, Biocartis' research partners published three papers and a study at ASCO[4] demonstrating the high quality of the Idylla™ tests on the market.
    - *Idylla™ ctBRAF Mutation Assay[5]:* A publication by Dr. Filip Janku, PhD, assistant professor of Investigational Cancer Therapeutics at MD Anderson Cancer Center (Houston, US) and his team[6] confirmed that the Idylla™ ctBRAF Mutation Assay can act as a faster and minimally invasive substitute for invasive tissue biopsy testing in advanced cancers such as melanoma or colorectal, which underlines that the test is

[1] Epidermal Growth Factor Receptor. The Idylla™ EGFR Mutation Assay is intended for Research Use Only (RUO), not for diagnostic procedures. Not for sale in the USA and Canada.
[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] Diaz LA, Jr., Bardelli A. Liquid biopsies: genotyping circulating tumor DNA. J Clin Oncol 2014; 32: 579–586; Siravegna G, Bardelli A. Genotyping cell-free tumor DNA in the blood to detect residual disease and drug resistance. Genome Biol 2014; 15: 449; and Montagut C, Dalmases A, Bellosillo B et al. Identification of a mutation in the extracellular domain of the Epidermal Growth Factor Receptor conferring cetuximab resistance in colorectal cancer. Nat Med 2012; 18: 221–223.
[4] American Society of Clinical Oncology.
[5] Intended for Research Use Only, not for diagnostic procedures. Not for sale in the USA and Canada.
[6] Janku et al. BRAF Mutation Testing in Cell-Free DNA from the Plasma of Patients with Advanced Cancers Using a Rapid, Automated Molecular Diagnostics System. Mol Cancer Ther (2016) 15(6): 1–8.

perfectly suited for treatment monitoring. Similar findings were reported by Prof. Bart Neyns (Head of Medical Oncology, University Hospital Brussels, Belgium) and his team[7].

- *Idylla™ KRAS Mutation Test*: A publication[8] by Prof. Troncone (University Federico II, Naples, Italy) researched the Idylla™ KRAS Mutation Test beyond the intended use of the test, in the setting of pancreatic cancer. The authors concluded[8] that the Idylla™ platform could easily be implemented in routine assessment of pancreatic DNA samples to quickly provide information on KRAS mutational status.
- *Idylla™ EGFR Mutation Assay[5]:* The new EGFR Mutation Assay was launched based on promising data from an alpha trial study which was accepted for publication at the upcoming ESMO meeting[9]. The study showed that the Idylla™ EGFR Mutation Assay demonstrated excellent specificity, sensitivity and ease of use combined with a fast turnaround time. Another study[10] by Prof. Troncone and colleagues (University Federico II, Naples, Italy) showed that >97% of lung cancer samples with insufficient DNA for Next Generation Sequencing (NGS) are still sufficient for testing with Idylla™. The study has been presented at the ASCO conference in June 2016.

- *Market potential*: Continued research shows that tumour mutation status (e.g. BRAF or KRAS) can drive several cancer types. Driven by such research, recently adopted ESMO guidelines[11] recommend that tumour BRAF mutation status should also be assessed alongside the tumour RAS mutational status in metastatic colorectal cancer (mCRC). Biocartis is uniquely positioned to respond to this new recommendation through its combined KRAS and NRAS-BRAF test offering in mCRC.

Infectious disease menu

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

- *Respiratory tests*: Biocartis' partner Janssen Diagnostics successfully concluded US clinical studies for the Idylla™ Respiratory (IFV-RSV) Panel in H1 2016 to pursue US FDA 510k[12] clearance. The FDA submission file is currently being finalised, with expected submission in H2 2016.
- Disease surveillance: On 1 June 2016, Biocartis received Emergency Use Authorisation (EUA) by the U.S FDA for the Idylla™ Ebola Virus Triage Test that may be used to detect Ebola Zaire virus in patients with signs and symptoms of Ebola virus disease. Apart from being the first FDA achievement, this was a milestone for Biocartis as the Idylla™ Ebola Virus Triage Test is also a first cornerstone in its disease surveillance test offer. A collaborative study on the Idylla™ Ebola Virus Triage Test by the Institute of Tropical Medicine, Janssen Pharmaceutica, NIH (Bethesda, US) and Biocartis was published in the Journal of Infectious Diseases[13], demonstrating that the Idylla™ test is fast, safe, easy to use and meets all performance criteria.

Financial highlights

- *Product revenues:* Total product revenues in H1 2016 grew 63% compared to H1 2015 from EUR 1.7m to EUR 2.7m. The increase in product revenues was driven by a strong growth in cartridge sales, which equalled EUR 1.7m in H1 2016 compared to EUR 0.4m in H1 2015 (increase of 314%). This was due to significantly higher commercial cartridge consumption and cartridges sold to Janssen Diagnostics for the US clinical studies of the Idylla™ Respiratory (IFV-RSV) Panel.
- *System revenues:* (i.e. Idylla™ Instrument and Idylla™ Console revenues) in H1 2016 amounted to EUR 1m compared to EUR 1.2m in H1 2015, representing a decrease of 21%. The cause of a decrease in system revenues is driven by an increased amount of commercial instruments that are placed with clients under different types of so-called operational lease contracts. These include a successful early adopter program which stimulates cartridge consumption at new customers, with the aim of securing long term commitments. Instrument revenues of operational lease contracts are recorded over the duration of the contract through lease payments made by customers.
- *Total operating income:* Total operating income in H1 2016 amounted to EUR 6.8m in H1 2016 compared to EUR 7.2m in H1 2015, representing a decrease of 7% due to increased product revenues that were offset by lower collaboration revenues. Collaboration revenues in H1 2016 included higher recognised upfront payments

[7] Schreuer et al. Quantitative assessment of BRAF V600 mutant cell-free tumor DNA from plasma as a diagnostic and therapeutic biomarker in patients with BRAF V600 mutant melanoma. ASCO 2015.
[8] De Biase et al. 'Fully Automated PCR detection of KRAS Mutations on Pancreatic Endoscopic Ultrasound Fine Needle Aspirates'. J Clin Pathol 2016.
[9] Reijans et al. ESMO 2016, to be published on 6 October 2016.
[10] De Luca et al., J Clin Pathol 2016.
[11] E. Van Cutsem et al, ESMO consensus guidelines for the management of patients with metastatic colorectal cancer, Annals of Oncology Advance Access published July 5, 2016.
[12] 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.
[13] Cnops et al. Development, Evaluation, and Integration of a Quantitative Reverse-Transcription Polymerase Chain Reaction Diagnostic Test for Ebola Virus on a Molecular Diagnostics Platform. J Inf Dis 2016. doi: 10.1093/infdis/jiw150.

from strategic partners compared to H1 2015 (increase of 30%) but lower milestone payments (decrease of 100%) since one-off milestone payments of EUR 2m were received in H1 2015 whereas no milestone payments were collected in H1 2016.

- *Financial debt:* Post reporting date, 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 finance the equipment of Biocartis' second cartridge manufacturing line and was signed before 30 June 2016. The other elements of the announced financing were signed in July 2016. As such, equipment investments for the second cartridge manufacturing facility made since initiation of the project in Q4 2015, were refinanced end of Q2 2016 with available lease financing. Following the above and including existing loans and lease facilities, total financial debt amounted to EUR 16.5m on 30 June 2016 compared to EUR 10.8m end of 2015.
- *Net cash flow:* Driven by increased operational expenses and higher investments for cartridge manufacturing expansion, of which most was refinanced with lease financing, the total net cash flow for H1 2016 amounted to EUR -28.3m.
- *Cash position:* Biocartis' cash position on 30 June 2016 amounted to EUR 75.8m compared to EUR 104.1m end of 2015 and approx. EUR 84m end of Q1 2016 (unaudited).

Commenting on the H1 2016 results, Rudi Pauwels, Chief Executive Officer of Biocartis, said: "*The year 2016 for Biocartis is focused on translating our investments in installed base growth and menu expansion to exponentially increase the number of patients that can be helped by our solutions. I am pleased to see first evidence of this materialising in H1 2016. We managed to strengthen our financial position with a new non-dilutive financing of EUR 55m that we announced in July 2016. This financing will further support us in realising our ambitious growth trajectory that is aimed at making high quality molecular diagnostic solutions available - everywhere and every time healthcare workers and patients interact and need to make clinical and therapeutic decisions.*"

Outlook 2016

- *Installed base:* Following the H1 2016 performance, guidance for the installed base expansion is increased to the top end of the 150-175 range, bringing the forecasted total installed base to around 340 Idylla™ instruments by year end.
- *Menu expansion:* Guidance for launching at least four new tests in 2016 reiterated. The following test launches are expected in H2 2016:
  - Liquid biopsy version of the Idylla™ KRAS Mutation Assay (RUO); and
  - Liquid biopsy version of the Idylla™ NRAS-BRAF Mutation Assay (RUO).
- *Regulatory events:* The following regulatory events for existing Idylla™ tests are expected in H2 2016:
  - CE-marking of Idylla™ NRAS Mutation Test and Idylla™ NRAS-BRAF Mutation Test solid biopsy tests;
  - US FDA 510k submissions for the Idylla™ Respiratory (IFV-RSV) Panel and the Idylla™ Instrument and Idylla™ Console; and
  - Continued product registration activities in other global markets, including South America, Latin America and Southeast Asia.
- *Expected publication:* Biocartis expects a publication by a renowned pharma company on an important study showing the key differences across a large number of KRAS Mutation detection technologies, incl. the Idylla™ KRAS Mutation Test, and their relevance in clinical practice, at the upcoming ESMO meeting in October 2016.
- *Cash position:* Guidance on target cash position by end 2016 in the range of EUR 45m to EUR 55m reiterated.

Key figures for H1 2016

The tables below show an overview of the key figures and a breakdown of operating income for H1 2016. Consolidated financial statements including notes are included in Biocartis' financial report for H1 2016 that can be downloaded from the Company's website here.

Key figures *(EUR 1,000)*	H1 2016	H1 2015	% Change
Total operating income	**6,750**	**7,224**	**-7%**
Cost of sales	-1,921	-1,158	66%
Research & Development expenses	-20,699	-16,092	29%
Marketing & Distribution expenses	-5,259	-3,219	63%
General & Administrative expenses	-2,874	-3,578	-20%
Operating expenses	**-30,754**	**-24,047**	**28%**
Operational result	**-24,003**	**-16,823**	**43%**
Net financial result	-282	-429	-34%
Income tax	501	337	49%
Net result	**-23,784**	**-16,915**	**41%**
Cash flow from operating activities	-25,345	-8,719	191%
Cash flow from investing activities	-6,912	-1,679	312%
Cash flow from financing activities	3,919	127,977	-97%
Net cash flow	**-28,338**	**117,579**	**-124%**
Cash and cash equivalents[1]	**75,757**	**128,477**	**-41%**
Financial debt	16,544	10,815	53%

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

Breakdown operating income (EUR 1,000)	H1 2016	H1 2015	% Change
Collaboration revenue	**3,377**	**4,866**	**-31%**
Idylla™ System Sales	988	1,246	-21%
Cartridge Sales	1,723	416	314%
Product sales revenue	**2,711**	**1,663**	**63%**
Service revenue	20	48	-58%
Total revenue	**6,109**	**6,577**	**-7%**
Grants and other income	641	646	-1%
Total operating income	**6,750**	**7,224**	**-7%**

Income statement

Collaboration revenues in H1 2016 showed an increase of recognised upfront payments that were received from strategic partners compared to H1 2015 (increase of 30%). No milestone payments were collected in H1 2016 compared to the EUR 2m of one-off milestone payments that were collected in H1 2015. This caused total collaboration revenues to decrease in H1 2016 to EUR 3.4m (EUR 4.9m in H1 2015). Product sales in H1 2016 increased with 63% compared to H1 2015 to EUR 2.7m. Grants and other income in H1 2016 consisted of various R&D project grants. Total operating income in H1 2016 amounted consequently to EUR 6.8m versus EUR 7.2m in H1 2015.

Total operating expenses in H1 2016 equalled EUR 30.8m compared to EUR 24.0m in H1 2015, an increase of 28% driven by higher expenses in R&D as well as in Marketing and Distribution. R&D expenses increased from EUR 16.1m in H1 2015 to EUR 20.7m in H1 2016 (increase of EUR 4.6m) as consequence of a growth of the R&D team to support continued menu and platform expansion as well as to support life cycle management for the increased number of on-market products. Marketing and distribution expenses increased from EUR 3.2m in H1 2015 to EUR 5.3m in H1 2016 (increase of EUR 2.0m) as consequence of an expansion of the sales team and higher sales and promotional expenses. G&A expenses decreased in H1 2016 to EUR 2.9m compared to EUR 3.6m in H1 2015, driven by one-off expenses for external advice in H1 2015 related to the Company's initial public offer (IPO) on Euronext Brussels. The above resulted in an operational result for H1 2016 equal to EUR -24.0m compared to EUR 16.8m in H1 2015 (decrease of EUR -7.2m). Following a net financial result for H1 2016 of EUR -0.3m and positive income taxes of EUR 0.5m, the net result for H1 2016 equalled to EUR -23.8m compared to EUR -16.9m for the same period in 2015.

Balance sheet
Property, plant and equipment increased in H1 2016 to EUR 17.0m from EUR 14.2m at the end of 2015 (increase of EUR 2.8m) driven by capital expenditure additions in H1 2016 of EUR 4.8m and a depreciation charge of around EUR 2.0m.

Inventory increased from EUR 5.8m per 31 December 2015 to EUR 9.0m per 30 June 2016 (increase of EUR 3.2m) driven by an overall higher instrumentation and cartridge inventory in light of expected increased commercialisation in H2 2016 and due to Idylla™ systems that are placed at customers under the Company's early adopter program. Trade receivables in H1 2016 decreased from EUR 5.9m end of 2015 to EUR 2.1m due to the collection of upfront and milestone payments from strategic partners recorded end of 2015. Trade payables end of H1 2016 amounted to EUR 6.7m which is a decrease of 7.3m compared to the EUR 13.9m as per 31 December 2015, mainly driven by the payment of advance invoices in relation to the second cartridge manufacturing line that were recorded end of 2015. Deferred income has decreased to EUR 3.6m per 30 June 2016, from EUR 5.2m per 31 December 2015, mainly because of recognised upfront payments from Janssen Pharmaceutica in relation to the strategic licensing, development and commercialisation collaborations.

Total financial debt increased from EUR 10.8m as of 31 December 2015, to EUR 16.5m per 30 June 2016 (an increase of EUR 5.7m) driven by the new lease and bank financings for the manufacturing expansion.
The cash position of the Group on 30 June 2016 amounted to EUR 75.8m compared to EUR 104.1m per 31 December 2015.

Cash flow statement
The cash flow from operating activities in H1 2016 amounted to EUR -25.3m compared to EUR -8.7m H1 2015. This increase is the result of higher operating expenses and investments in working capital for H1 2016 compared to significant positive movements in working capital for H1 2015. The cash flow from investing activities in H1 2016 amounted to EUR -6.9m compared to EUR -1.7m in H1 2015 principally driven by the increased capital expenditure for the cartridge manufacturing expansion. The cash flow from financing activities in H1 2016 amounted to EUR 3.9m, mainly driven by proceeds of the lease and bank financing for the cartridge manufacturing equipment. In H1 2015 the cash flow from financing activities amounted to EUR 128.0m thanks to the cash inflow from the IPO (EUR 107.0m) in April 2015 and the capital increase of the second tranche of the series F round (EUR 21.5m) in January 2015. The Group's net cash flow in H1 2016 amounted to EUR -28.3m.

Financial calendar
- Q3 Business Update 2016: 17 November 2016
- Full year results 2016: 2 March 2017

Webcast and presentation
The Biocartis management team will host a conference call with live webcast, during which the H1 2016 results will be presented, followed by a Q&A session. This event will be held today, 6 September 2016 at 14:00 CEST. The webcast can be accessed by clicking here. If you would like to participate in the Q&A, please dial +44(0)20 3427 1908 (standard international) with confirmation code 6014209. 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 2016 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 2015. 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 1 September 2016. 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 2016 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 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_.