



REGULATED INFORMATION

PRESS RELEASE

BIOCARTIS Q3 2015 BUSINESS UPDATE

Mechelen, Belgium, 19 November 2015: Biocartis (Euronext Brussels: **BCART**), an innovative molecular diagnostics company, today provides a business update for the third quarter of 2015 and outlook for the coming months.

Key messages

- Commercial ramp up continued well in Q3 2015, on track to reach 2015 full year guidance of 75 instruments sold.
- Strong progress in test menu development in Q3 2015 and on track for three Idylla™ test launches before year end:
 - First CE-IVD test for infectious diseases (Idylla™ IFV-RSV Panel, expected before end November);
 - First liquid biopsy test (BRAF liquid biopsy test for melanoma cancer, launched as Research Use Only – RUO); and
 - Second test for colon cancer (RUO NRAS/BRAF/EGFR492 test).
- Cash position end of Q3 2015 amounts to approx. EUR 113.6m (including a EUR 4.1m one-time repayment of the Senter Novem loan, consisting of the full principal repayment and EUR 1.3m of accumulated interest).

Commenting on the Q3 2015 business update, Rudi Pauwels, Chief Executive Officer of Biocartis, said: *"Following a strong first half of 2015, in which Biocartis amongst others successfully completed its IPO and received CE-IVD marking for its KRAS Mutation Test for colorectal cancer, we are pleased to announce that we continue to execute well upon our business plan in Q3 2015.*

Operationally, we predominantly focused on enabling the launches of three new Idylla™ tests in Q4 2015, of which our Idylla™ IFV-RSV panel is expected to be the first one, which is to be followed by two oncology tests. Furthermore, our own sales force and distribution partners made good progress in further expanding our installed base.

Our key focus for the remainder of this year as well as for 2016 is to establish a core menu for oncology and to launch our first wave of infectious disease tests. By doing so, we expect to significantly grow the installed base of our Idylla™ platform. This will allow more patients to benefit from more efficient and cost-effective high precision diagnostics to enable higher precision medicine solutions. These serve society with an improved healthcare outcome, at an affordable price and compatible with sustainable healthcare."

Menu update

During Q3 2015, Biocartis further advanced the development of new tests for Idylla™, its fully automated sample-to-result, real-time molecular diagnostics system that offers accurate, highly reliable molecular information from virtually any biological sample in virtually any setting. Test menu development at Biocartis is focused on addressing unmet clinical needs in oncology and infectious diseases, being respectively the

fastest growing and largest segment of the worldwide molecular diagnostics market¹. Biocartis aims to launch four to five Idylla™ tests per year.

Menu oncology tests

- *Solid biopsy menu*
 - During Q3 2015, Biocartis further advanced the development of its solid biopsy NRAS test (colon cancer²) and LCP test (lung cancer panel). The NRAS test and LCP test will complement Biocartis' CE-IVD marked solid biopsy BRAF Mutation Test and KRAS Mutation Test. Together, these four tests offer an attractive menu to pathologists by detecting a total of 98 targets, including all clinically actionable mutations in KRAS, NRAS and BRAF.
 - Biocartis presented mid-September at the 40th European Cancer Congress 2015 (Vienna, Austria) a study called '*A solution for same-day extended RAS testing*'. This study puts forward the importance of using the Idylla™ CE-IVD KRAS Mutation Test in conjunction with the Idylla™ NRAS test that is under development, as that allows for complete RAS testing in less than three hours ('same day solution') from just two slices of so-called 'Formalin Fixed Paraffin Embedded' (FFPE) tumour tissue. Furthermore, these tests uniquely detect a wide range of 40 KRAS and NRAS mutations at high sensitivity, meeting the novel clinical guidelines as recently issued by ASCO/AMP/NCI³ (including 5% limit of detection).
- *Liquid biopsy menu* – Biocartis is developing liquid biopsy versions of its solid biopsy tests. During Q3 2015, focus was on the progress of the BRAF liquid biopsy test. In addition, progress has been made in the development of liquid biopsy versions of the Idylla™ extended RAS tests (i.e. KRAS and NRAS). A study, '*Fully automated, plasma-based analysis of circulating tumour DNA on the Idylla™ platform*', was presented at the World Companion Diagnostics meeting (Boston, US) beginning of September. This study showed that Biocartis' extended RAS tests in tissue and blood could help clinicians with a wide range of potential applications for inclusion in targeted therapies, for monitoring of efficacy, and for following upcoming resistance.

Menu infectious diseases tests

- *Idylla™ IFV-RSV Panel* – During Q3 2015, Janssen Diagnostics, in collaboration with Biocartis, finalised the validation studies of the first infectious disease test for use on the Idylla™ system. The test, known as the Idylla™ Influenza-Respiratory Syncytial Virus Panel, is intended for the detection of various strains of Influenza Virus (IFV) and Respiratory Syncytial Virus (RSV) in nasopharyngeal swabs to aid in the diagnosis of viral respiratory disease. The Idylla™ IFV-RSV Panel is expected to receive CE-IVD marking and to be ready for commercial use in Europe and other geographies accepting the CE-mark before end of November. Janssen Diagnostics has appointed Biocartis as co-exclusive worldwide distributor of the Idylla™ IFV-RSV Panel.
- *Multiplex Respiratory Panel* – In May 2015, Biocartis and Fast-track diagnostics entered into a strategic collaboration to develop a range of multiplex infectious disease tests for the Idylla™ platform. During Q3 2015, the parties advanced the development of an Idylla™ Multiplex Respiratory Panel. The test is expected to detect a range of over 20 viral and bacterial pathogens commonly found in upper respiratory tract infection.
- *MERS test* – During Q3 2015, Biocartis and Fast-track diagnostics initiated the development of a test aimed at detecting MERS-CoV. MERS-CoV is a type of coronavirus that was first identified in Saudi Arabia in 2012 and is the cause of Middle East Respiratory Syndrome (MERS). A large outbreak of this disease occurred in South-Korea in 2015 and approximately 36% of patients with MERS reported to date have died⁴. The MERS test will further complement Biocartis' offering of respiratory tests.
- *Ebola test* – The Rapid Ebola Virus Triage Test that Biocartis is developing in association with Janssen Diagnostics and the Institute for Tropical Medicine in Antwerp (Belgium) for its Idylla™ system was

¹ Source: Markets and Markets – Molecular Diagnostics Market, Global Forecast to 2018 (August 2014).

² Biocartis is developing three versions of its NRAS test to meet demand of clients in different geographies; the first one (NRAS) detects 19 mutations in the NRAS gene, the second one (NRAS/BRAF) detects in addition BRAF codon 600 mutations and the third one (NRAS/BRAF/EGFR492) also detects the EGFR S492R mutation.

³ ASCO = American Society of Clinical Oncology, AMP = Association for Molecular Pathology and NCI = National Cancer Institute.

⁴ Source: World Health Organization, Fact sheet N°401.

further progressed in Q3 2015, including studies conducted on live Ebola viruses in the highest biosafety level laboratories of the National Institute of Health (Maryland, USA). Biocartis expects to submit the required documentation for an emergency use authorisation (EUA) application to the Federal Drug Administration (FDA) before the end of November.

Commercial update

- *Commercial footprint* – During Q3 2015, Biocartis further expanded its global sales and distribution network, now covering over 55 countries globally by adding direct sales activities and signing new distribution agreements.
- *Direct sales force* – Biocartis' sales force strengthened its capabilities within the infectious disease field to support the market launch of the Idylla™ IFV-RSV Panel Test.
- *Liquid biopsy marketing* – In Q3 2015, Biocartis started several marketing initiatives to support the launch of its liquid biopsy tests. Amongst others, market surveys with key opinion leaders were conducted and development of a new branding campaign was initiated.

Outlook

- *Installed base guidance* – Driven by the commercial activities in Q3 2015 and performance of H1 2015, Biocartis keeps its target of selling 75 instruments in 2015 unchanged, growing its installed base to over 150 in 2015.
- *Oncology menu* – Research Use Only (RUO) launches of the BRAF liquid biopsy and NRAS/BRAF/EGFR492 test are expected before year end.
- *Infectious diseases menu* – CE-IVD marking and market launch of Idylla™ IFV-RSV Panel and completion of the EUA submission for the Rapid Ebola Virus Triage Test expected before end of November.
- *Outsourcing instrumentation production* - The outsourcing process of the Idylla™ Instrument and Console production to a Contract Manufacturing Organization is on track and expected to be completed before year end.
- *Idylla™ menu update* – Biocartis will host a Capital Markets Day tailored for institutional investors, research analysts and sector journalists in Q1 2016 to provide amongst others an update on the future Idylla™ menu.

For more information, please contact:

Biocartis

Renate Degrave (Corporate Communications & Investor Relations)

+32 15 632 600 | press@biocartis.com

Consilium Strategic Communications

Amber Fennell, Jessica Hodgson, Chris Welsh, Hendrik Thys

+44 (0) 203 709 5701 | biocartis@consilium-comms.com

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. Idylla™ addresses the growing demand for personalized medicine by allowing fast and effective treatment selection and treatment progress monitoring.

Biocartis launched the Idylla™ platform commercially in September 2014 together with its first assay to identify BRAF Mutations in metastatic melanoma. Its second assay, a KRAS Mutation panel for colorectal cancer has been launched in June 2015. 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. Further information can be found at: www.biocartis.com.

About Idylla™ (www.idylla.com)

Idylla™, Biocartis' fully automated, real-time PCR based molecular diagnostics system, is designed to offer fast and easy access to clinical molecular diagnostic information, anywhere and anytime. The Idylla™ platform covers the entire process from sample to result in a time frame of 35 to 150 minutes with less than two minutes hands-on time. Idylla™ is applicable for a wide range of clinical sample types and can analyse both RNA and DNA. The fully integrated system enables clinical laboratories to perform a broad range of applications in oncology, infectious diseases and beyond. Idylla™ and the system's first assays, the Idylla™ BRAF Mutation Test for metastatic melanoma and Idylla™ KRAS Mutation Test for colorectal cancer have obtained CE-IVD marking.

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