

Biocartis and A*STAR's ETPL initiate development of breast cancer assay to guide therapy selection

Singapore / Mechelen (Belgium), 10 July 2017 - Biocartis Group NV ('Biocartis' or the 'Company'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announced that it has extended its partnership with ETPL (the commercialization arm of A*STAR, Singapore's Agency for Science, Technology and Research¹) with a new five-year strategic partnership, focused on the development of molecular diagnostic assays for Biocartis' Idylla™ platform, 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. The first assay selected for development under the partnership is a fully automated solid biopsy assay, aimed at supporting optimal therapy selection decisions for breast cancer patients.

Under the terms of the agreement, parties will co-invest in the development of jointly selected tests. For each selected test, Biocartis will be responsible for the commercialization of the tests under its own label, while ETPL will act as a development partner through Singapore's Diagnostics Development (DxD) Hub. Financial details of the partnership are not disclosed.

The first assay selected for development under the new partnership is a fully automated solid biopsy assay, operating directly from FFPE² tumor tissue and aimed at supporting optimal therapy selection for Her2-targeted therapies³, hormone receptor therapies, as well as some novel targets for breast cancer patients.

Breast cancer is the most common cancer among women worldwide⁴ and the largest segment of the cancer diagnostics market⁵, expected to account for USD 13.1bn by 2020⁶. Current breast cancer diagnostic testing methods comprise complex and lengthy workflows, involving numerous manual steps and visual interpretation of results. Consequently, specificity and reproducibility of these test methods are challenging with both false positive and false negative test results occurring commonly⁷. Also, as today's methods require specific laboratory expertise and samples need to be shipped for such analyses, it often takes a long time before results are available.

Furthermore, an increasing number of targeted and hormone therapies for breast cancer drives the demand for assays that guide therapy selection. Among other biomarkers, the assay will include Her2, which is a major prognostic biomarker shown to occur in 18-20% of breast cancers⁸ and which is currently recommended for the evaluation of primary invasive breast cancer. Hormone receptor therapy, which has the potential to be used in about two-thirds of women with breast cancer tumors that show hormone receptor expression⁹, is currently part of the routine tumor characterization process¹⁰.

Being Biocartis' second assay¹¹ in the breast cancer segment and an important addition to Biocartis' menu of tests next to its current focus on melanoma, lung and colorectal cancer, the assay has the potential to enable fast and robust results and as such, make a real difference with current testing methods.

Geert Maertens, Chief Scientific Officer of Biocartis, commented: *"By combining the expertise and network of ETPL and Biocartis, this partnership agreement has laid the foundation to bring more high performing Idylla™*

¹ 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.

² Formalin-fixed, paraffin embedded.

³ Her2 is a major prognostic marker that is currently recommended for the evaluation of primary invasive breast cancer, also known as 'human epidermal growth factor receptor 2' or Her2. Gene amplification and overexpression of Her2 are present in 18-20% of breast cancers. Studies have also shown that Her2 protein overexpression is associated with worse overall survival and twice the mortality rate compared with women with no Her2 expression. Source: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2758104/>, last consulted on 8 June 2017.

⁴ 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.

⁵ Source: GrandView Research, "Cancer Diagnostics Market Analysis By Type (Laboratory Tests, Genetic Tests, Imaging, Endoscopy), By Application (Breast, Lung, Liver, Cervical, Colorectal, Skin), By Region, And Segment Forecasts, 2014 - 2025", <http://www.grandviewresearch.com/industry-analysis/cancer-diagnostics-market>, last consulted on 15 May 2017.

⁶ Source: MarketsandMarkets, "Cancer Diagnostics Market by Technology (ELISA, ELFA, PCR, NGS, Immunohistochemistry, Microarray, Imaging (MRI, CT, PET, Ultrasound, Mammography), Biopsy), by Application (Breast Cancer, Lung Cancer, Colorectal Cancer, Melanoma) - Forecast to 2020", 2015.

⁷ Source: NCCN Breast Cancer Guidelines v2.2016.

⁸ Source: <https://www.mycancergenome.org/content/disease/breast-cancer/erbb2/238/>, last consulted on 27 June 2017.

⁹ Source: <http://www.webmd.com/breast-cancer/breast-cancer-hormone-therapy-choices#1>, last consulted on 9 June 2017.

¹⁰ Source: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2758104/>, last consulted on 8 June 2017.

¹¹ On 7 June 2017, Biocartis announced a partnership with LifeArc (formerly known as MRC Technology) to develop selected molecular diagnostic tests for use on Biocartis' fully automated Idylla™ platform, with a liquid biopsy test aimed at monitoring of metastatic breast cancer patients for resistance to hormone therapy as a first test to be developed under the partnership.

assays to the market in a shorter timeframe. We are thrilled to work with ETPL for the development of our second⁵ breast cancer assay, this time aimed at supporting decisions for a rapidly growing number of targeted and hormone receptor therapies for breast cancer patients."

Sidney Yee, CEO of the DxD Hub, and Executive Vice-President of ETPL said: *"We are pleased to announce today an extension of our partnership with Biocartis, a global player in molecular diagnostics at the forefront of innovation. Over the years, Singapore's investment in research and development has established a strong base of technological capabilities and produced a pipeline of cancer biomarkers. ETPL's partnership with Biocartis is an excellent opportunity for us to accelerate the creation of diagnostics innovations that will serve the growing needs for early diagnosis of cancer, better patient monitoring and care, and lower health care costs."*

The extended agreement fits well with Biocartis' strategy to accelerate the expansion of its menu of molecular diagnostic tests through third party partnerships, and aligns with Singapore's vision to develop globally competitive products and grow the local diagnostics ecosystem.

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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. More information: www.biocartis.com. Press Photo Library available [here](#). Follow us on [Twitter](#): @Biocartis_.

About ETPL

ETPL is the commercialization arm of the Agency for Science, Technology and Research (A*STAR), Singapore's lead agency for fostering world-class scientific research and talent. As a one-stop resource, ETPL supports A*STAR in transforming the economy through driving innovation and commercializing its research outcomes. ETPL enhances the research output of A*STAR scientists by translating their inventions and intellectual capital into marketable products, processes and services. Through shaping and facilitating licensing deals and spin-offs, ETPL actively engages industry leaders and players to commercialize A*STAR's technologies and apply them to building ecosystems that benefit business, industry and economy. For more information, please visit <http://www.etpl.sg>.

About the Diagnostics Development (DxD) Hub

The Diagnostics Development (DxD) Hub is a national initiative in Singapore, led by the Agency for Science, Technology and Research (A*STAR) and managed by A*STAR's commercialisation arm ETPL. The DxD Hub aims to accelerate the transformation of innovations into clinically validated diagnostic devices that are ready for market adoption. Through impactful products, empowering local enterprises and anchoring global companies in Singapore, the DxD Hub contributes to the development of an effective diagnostic devices ecosystem in Singapore.

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