PRESS RELEASE 4th April 2023

Biocartis and APIS Assay Technologies Sign Collaboration to Develop and Commercialize a Breast Cancer Subtyping Test on the Idylla™

Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), and APIS Assay Technologies Ltd., a private UK company specialising in molecular diagnostics, today announce that they have entered into a new partnership agreement which targets the development of APIS' Breast Cancer Subtyping assay on Biocartis' rapid and easy-to-use molecular diagnostics platform Idylla™.

Under the terms of the partnership agreement, APIS will lead the development of the Breast Cancer Subtyping test on Idylla™, while Biocartis will lead the commercialisation through its growing Idylla™ network.

Breast cancer is the most commonly diagnosed cancer among women, accounting for 11.7% of all cancer cases globally[i]. In 2020, it was estimated that there were over 2.2 million new cases of breast cancer worldwide[i]. Invasive breast cancer is classified into distinct categories with differing tumour behaviour and prognosis[ii]. Based on the expression of hormone receptors that are present in breast cancer cells (HER2, ER, PR)[iii] and a proliferation marker (Ki67)[iv], the main molecular subtypes of invasive breast cancer can be distinguished.[v] The presence or absence of these markers can guide the selection of appropriate treatment options. ER and PR are important indicators of how well a breast cancer tumour will respond to hormone therapy. HER2, on the other hand, is an important predictor of response to targeted therapy, such as trastuzumab[vi]. The detection of these markers is routinely performed with IHC[vii]

APIS' current Breast Cancer Subtyping Kit is an RNA-based diagnostic assay for detecting mRNA expression of standard biomarkers (HER2, ER, PR, Ki67) and novel proliferative biomarkers from pre-operative core-needle biopsy (CNB) or resected formalin-fixed paraffin-embedded (FFPE) breast tumour tissue. The test aims to address a number of unmet needs in current practice, including improving reproducibility and accuracy in the Ki67 proliferation measurement and assessment of low HER2 expression status. The latter is especially important as recent studies have shown HER2-low patients to be responsive to a new category of HER2 targeting therapies.[viii,ix]

Currently, the APIS Breast Cancer Subtyping Kit is available as a manual kit for in vitro diagnostic use[x], mainly addressing centralized expert laboratories. The kit is currently offered by APIS in the UK and will be broadly commercialized[xi] by Biocartis ahead of the Idylla™ version of the assay becoming available. While the manual kit already offers a reduced time for results interpretation (as compared to current IHC based workflows), the Idylla™ version of the Breast Cancer Subtyping assay will further benefit from the workflow and decentralization advantages of the Idylla™ platform. This is expected to allow for the fastest time to results and for improved access to the most accurate biomarker results for patients worldwide.

Herman Verrelst, Chief Executive Officer of Biocartis, commented: "We are excited about partnering with APIS Assay Technologies to improve molecular classification for breast cancer patients. The APIS team is highly experienced in IVD development and will lead the porting of the assay to our Idylla™ platform. Our sales team has become highly proficient in distribution of manual kits across its extensive laboratory network, while developing Idylla™ version of partner assays. The combination of the APIS Breast Cancer Subtyping test with the Idylla™ PIK3CA-AKT1 Mutation Assay that is under development will allow us to offer a complementary set of assays in the breast cancer domain."

Joachim Schorr, Chief Executive Officer of APIS Assay Technologies, added: "We are very much looking forward to our collaboration with the Biocartis team. The Idylla™ platform and its all-in-one cartridge based tests provide an optimised, fully automated, solution for fast and effective treatment selection for breast cancer patients. Furthermore, Biocartis' global presence will further allow our innovative solution to benefit breast cancer patients worldwide. The collaboration with Biocartis will provide the ability to perform Breast Cancer Subtyping analysis also directly in pathology labs utilising the Idylla™ platform's ease of use and integrated FFPE sample-to-result performance."

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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 is developing and marketing a continuously expanding test menu addressing key unmet clinical needs, with a focus in oncology, which represents the fastest growing segment of the MDx market worldwide. Today, Biocartis offers tests supporting melanoma, colorectal and lung cancer, as well as for COVID-19, flu, RSV and sepsis. More information: www.biocartis.com. Follow us on Twitter: @Biocartis_,Facebook or LinkedIn

About APIS
APIS is leveraging systems biology, interrogating multi-OMICs biodata, and deploying innovative 'Clickmer' ligand binding technology, for the validation and translation of biomarker and therapeutic assets into clinical utility. APIS has deep expertise and capabilities in IVD development of molecular & immune-assays for ultimate product realisation as diagnostic tests. In addition, APIS' expertise in bioinformatics and software development is offered as an agile service to our clients, to develop bespoke, end-to-end multi-OMICs solutions and platform development. The new APIS Breast Cancer Subtyping Kit is a highly reproducible, RT-qPCR based IVD product (in certain territories[x]) and RUO product for detecting standard (HER2, ER, PR, Ki67) and novel proliferative biomarkers. The results of this assay can help direct clinicians to the right treatment, more quickly, with higher accuracy. For more information, visit https://www.apisassay.com/, or follow APIS on Twitter @ApisAssay or LinkedIn.

[i] WHO Globocan; https://gco.iarc.fr/today/data/factsheets/cancers/20-Breast-fact-sheet.pdf
[ii] 13th St. Gallen International Breast Cancer Conference 2013, Expert panel consensus opinion.
[iii] ER: estrogen receptor, PR: progesterone receptor, HER2: human epidermal growth factor receptor 2
[iv] Ki67: marker of proliferation Ki-67
[v] Four main molecular subtypes: Luminal A, Luminal B, HER2, and Basal-like (triple negative)
[vi] Trastuzumab, sold among others under the brand name Herceptin®, is a monoclonal antibody used to treat HER2-positive breast cancer.
[vii] IHC: immunohistochemistry, a process in which the presence of proteins is revealed by staining tissue sections with labeled antibodies for subsequent visual inspection under a microscope.
[viii] Trastuzumab:deruxtecan (Enhertu®), an antibody-drug conjugate, is the first HER2-directed therapy approved for patients with HER2-low metastatic breast cancer.

[ix] Nicolò *et al.* The HER2-low revolution in breast oncology: steps forward and emerging challenges Ther Adv Med Oncol (2023) 15: 17588359231152842.

[x] Registered as IVD in the UK, awaiting CE marking under EU IVD Regulation
[xi] In the European Union and selected export markets