



PRESS RELEASE

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Biocartis Announces Expansion of its Collaboration with APIS Assay Technologies to Commercialize the APIS ESR1 Mutations Kit

Mechelen, Belgium, 12 October 2023 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company and APIS Assay Technologies Ltd. ('APIS'), a private UK based company specializing in molecular diagnostics, today announced the expansion of their partnership¹ to include the commercialization of the APIS ESR1 Mutations Kit through Biocartis' worldwide commercial network.

Roger Moody, Chief Executive Officer of Biocartis, commented: *"We are excited to expand our partnership with APIS Assay Technologies to commercialize the APIS ESR1 Mutations Kit. Together with the Idylla™ PIK3CA-AKT1 Mutation Assay and the APIS Breast Cancer Subtyping Kit we will be able to provide a comprehensive menu of products in the breast cancer domain to our customers. Our commercial team has been building a network within the breast cancer domain and we will be able to not only to leverage it but also to further expand it by adding the APIS ESR1 Mutations Kit on our product portfolio."*

Ian Kavanagh, Chief Executive Officer of APIS, added: *"We are very much looking forward to our further collaborations with the Biocartis team. Biocartis' global presence will allow a fast commercialization and worldwide roll out of the APIS ESR1 Mutations Kit. As we are currently developing the APIS Breast Cancer Subtyping Kit on the Idylla™ Platform, our teams are already working closely together and are fully up-to-speed to enable a broader availability of our innovative breast cancer assay portfolio, as well as to explore the opportunity of also developing a fully automated version of the APIS ESR1 Mutations Kit on the Idylla™ Platform."*

Breast cancer is the most common cancer diagnosed globally² and it is classified into different molecular subgroups according to hormone receptor and HER2 status. Estrogen Receptor-positive (ER+) breast cancer is the most common subtype of breast cancer and endocrine therapy is the main therapeutic option for this group. Most tumors, however, develop resistance to endocrine therapy as the cancer progresses.³ Several mechanisms of resistance have been described, including mutations in the estrogen receptor (ESR1) gene.⁴ ESR1 mutations are a common mechanism of endocrine resistance⁵ and are associated with a shorter progression-free survival⁶.

New therapeutic options are becoming available that have the potential to overcome ESR1 mutation-mediated resistance.⁷ ESR1 mutation monitoring has the potential for playing a key role in monitoring disease progression and appearance of resistance in breast cancer patients receiving endocrine therapy.^{8,9} Further research is, however, needed to better understand the potential value of ESR1 mutation monitoring.

The APIS ESR1 Mutations Kit is a qualitative, qPCR¹⁰ based, Research Use Only (RUO) product for the detection of ESR1 mutations in plasma samples. Biocartis will distribute the kit via its commercial network with an initial focus on Europe.

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More information:

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¹ The partnership between Biocartis NV and APIS was announced on 4 April 2023

² WHO Globocan; <https://gco.iarc.fr/today/data/factsheets/cancers/20-Breast-fact-sheet.pdf>

³ Colleoni et al. Annual Hazard Rates of Recurrence for Breast Cancer During 24 Years of Follow-Up: Results From the International Breast Cancer Study Group Trials I to V. *J Clin Oncol* (2016) 34: 927-35

⁴ Hartkopf et al. Endocrine-Resistant Breast Cancer: Mechanisms and Treatment. *Breast Care* (2020) 15: 347-54

⁵ Brett et al. ESR1 mutation as an emerging clinical biomarker in metastatic hormone receptor-positive breast cancer. *Breast Cancer Res.* (2021) 23: 85

⁶ Hernandez et al. Oral Selective Estrogen Receptor Degraders (SERDs) as a Novel Breast Cancer Therapy: Present and Future from a Clinical Perspective. *Int J Mol Sci* (2021) 22: 7812

⁷ Ferro et al. Oral selective estrogen receptor degraders (SERDs): The new emperors in breast cancer clinical practice? *Semin Oncol* (2023) 26: S0093

⁸ Li et al. Clinical Implications of Monitoring ESR1 Mutations by Circulating Tumor DNA in Estrogen Receptor Positive Metastatic Breast Cancer: A Pilot Study. *Transl Oncol* (2020) 13: 321-28

⁹ Zunderlevich et al. ESR1 mutations are frequent in newly diagnosed metastatic and loco-regional recurrence of endocrine-treated breast cancer and carry worse prognosis. *Breast Cancer Res* (2020) 22: 16

¹⁰ PCR (Polymerase Chain Reaction)

About Biocartis

With its revolutionary and proprietary Idylla™ Platform, Biocartis (Euronext Brussels: BCART) aspires to enable personalized medicine for patients around the world through universal access to molecular testing, by making molecular testing actionable, convenient, fast and suitable for any lab. The Idylla™ Platform is a fully automated sample-to-result, real-time PCR (Polymerase Chain Reaction) based system designed to offer in-house access to accurate molecular information in a minimum amount of time for faster, informed treatment decisions. Idylla™'s continuously expanding menu of molecular diagnostic tests address key unmet clinical needs, with a focus in oncology. This is the fastest growing segment of the molecular diagnostics market worldwide. Today, Biocartis offers tests supporting melanoma, colorectal, lung and liver cancer, as well as for sepsis. More information: www.biocartis.com. Follow us on [X \(Twitter\)](#): @Biocartis_.

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 realization 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 ESR1 Mutations Kit is an advanced qPCR based RUO product for the sensitive and precise detection of mutations within the estrogen receptor gene. The ESR1 Mutations Kit is a qualitative test, detecting eleven ESR1 mutations across three exons. It is applicable for use in both centralized and decentralized settings, especially for those facilities that require a testing solution without the need for additional specialised NGS or digital PCR instruments. For more information, visit <https://www.apisassay.com/>, or follow APIS on [X \(Twitter\)](#) @ApisAssay or [LinkedIn](#).

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