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Biocartis Honors Breast Cancer Awareness Month with Launch of Breast Cancer Portfolio

Mechelen, Belgium, 16 October 2023 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company, announces the launch of the new Breast Cancer Portfolio during the Breast Cancer Awareness month: the Idylla™ PIK3CA-AKT1 Mutation Assay and, in collaboration with APIS Assay Technologies ('APIS'), the APIS Breast Cancer Subtyping Kit and the APIS ESR1 Mutations Kit.

The **Idylla™ PIK3CA-AKT1 Mutation Assay (RUO[1])**, performed on the Biocartis Idylla™ Platform, is a fully automated real-time polymerase chain reaction (PCR) Assay for the qualitative detection of 13 mutations in the *PIK3CA* gene and one mutation in the *AKT1* gene in formalin-fixed, paraffin-embedded (FFPE) human tissue sections. The Idylla™ PIK3CA- AKT1 Mutation Assay, which was developed in collaboration with LifeArc, covers the entire process from FFPE sample to result, including fully integrated sample preparation, liberation of nucleic acids, real-time PCR amplification and detection, and data analysis. With a turnaround time of approximately 150 minutes, the Assay provides a rapid actionable solution which can be seamlessly integrated into virtually any laboratory workflow.

The **APIS Breast Cancer Subtyping Kit (RUO[1])** is a gene expression assay based on a real-time reverse transcription quantitative polymerase chain reaction (RT-qPCR). The kit detects and enables relative gene expression quantification of ten human mRNA target genes extracted from formalin-fixed, paraffin embedded (FFPE) pre-operative core needle biopsies (CNB) or FFPE resected breast tumour tissue. The manual kit will be distributed by Biocartis in selected European countries ahead of an Idylla™ version of the assay becoming available. While the manual kit already offers a reduced time for results interpretation (as compared to current IHC[2] based workflows), the future Idylla™ version of the Breast Cancer Subtyping Assay will further benefit from the workflow and decentralization advantages of the Idylla™ Platform.

The **APIS ESR1 Mutations Kit (RUO[1])** is an advanced real-time PCR assay for the sensitive and precise detection of mutations within the estrogen receptor gene. The kit detects eleven ESR1 mutations in circulating free DNA from plasma samples. Biocartis will distribute the manual kit via its commercial network with an initial focus on Europe and will explore, together with APIS, the opportunity of also developing a fully automated version of the APIS ESR1 Mutations Kit on the Idylla™ Platform.

Roger Moody, Chief Executive Officer of Biocartis, commented: "*With 1 in 8 women diagnosed with breast cancer in her lifetime, it is important to us to deliver continuous improvements in patient care during Breast Cancer Awareness Month. While we have seen marked improvements in outcomes for early detected breast cancer, metastatic breast cancer remains a significant challenge. I am very pleased that Biocartis can contribute to the further research of this important disease by launching three new biomarker assays at once. We are fortunate to collaborate with APIS to make these innovative products available to our customers.*"

Breast cancer is the most commonly diagnosed cancer among women, accounting for 11.7% of all cancer cases globally. Annually, it is estimated that there are over 2.3 million new cases of breast cancer worldwide.[3] Despite recent advances in treatment strategies leading to improved survival, metastatic breast cancer remains largely incurable and is responsible for over 600,000 deaths annually worldwide.[4,5] The American Cancer Society reports a five-year survival rate of 99% for localized breast cancer and only 27% for breast cancers with distant metastases[2].

[1] For research use only (RUO), not for use in diagnostic procedures.

[2] 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.

[3] WHO Globocan; https://gco.iarc.fr/today/data/factsheets/cancers/20-Breast-fact-sheet.pdf

[4] Hagio et al. (2021). Impact of clinical targeted sequencing on endocrine responsiveness in estrogen receptor-positive, HER2-negative metastatic breast cancer. *Scientific reports* (11)1, 8109. doi: 10.1038/s41598-021-87645-6

[5] Garrido-Castro et al. (2021). Genomic Characterization of de novo Metastatic Breast Cancer. *Clinical Cancer Research*, (27)4, 1105-1118. doi: 10.1158/1078-0432.CCR-20-1720

Invasive breast cancer is classified into distinct categories with differing tumor behavior and prognosis.[6] Based on the expression of hormone receptors that are present in breast cancer cells (HER2, ER, PR)[7] and a proliferation marker (Ki67)[8] , the main molecular subtypes of invasive breast cancer can be distinguished.[9,10] The presence or absence of these markers can guide patient management. The detection of these markers is routinely performed with IHC. The **APIS Breast Cancer Subtyping Kit** aims to address a number of unmet needs in the current practice, including improving reproducibility and accuracy in the Ki67 proliferation measurement, assessing low HER2 expression status and offering faster subtyping as compared to IHC.

The most common breast cancer subtype is Estrogen Receptor-positive (ER+) breast cancer and endocrine therapy is the main therapeutic option for this group. While endocrine therapy is effective, as cancer progresses, many tumors, eventually become resistant.[11] Mutations in the estrogen receptor (ESR1) gene are a common mechanism of endocrine resistance[12,13] and are associated with a shorter progression-free survival.[14] New therapeutic options are becoming available that have the potential to overcome ESR1 mutation-mediated resistance.[15] 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.[16,17] Further research is, however, needed to better understand the potential value of ESR1 mutations monitoring and the **APIS ESR1 Mutations Kit** aims to be a valuable tool to support such research.

The PI3K/AKT/mTOR signaling pathway is an important cell signaling pathway with an important role in cell growth, proliferation, survival, and metabolism.[18] In breast cancer this pathway is deregulated in as much as 40% of hormone receptor-positive, HER2-negative metastatic breast cancer patients. A common mechanism of such deregulation are somatic mutations in the PIK3CA or AKT1 genes. New therapeutic options are becoming available that target mutated PIK3CA or AKT1[19,20] and require new tools to aid in the sensitive detection of relevant gene mutations. The **Idylla™ PIK3CA-AKT1 Mutation Assay** aims to offer a sensitive, rapid and easy-to-use tool to further study the role of PIK3CA and AKT1 mutations in metastatic breast cancer.

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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

[6] 13th St. Gallen International Breast Cancer Conference 2013, Expert panel consensus opinion.
[7] ER: estrogen receptor, PR: progesterone receptor, HER2: human epidermal growth factor receptor 2
[8] Ki67: marker of proliferation Ki-67
[9] Four main molecular subtypes: Luminal A, Luminal B, HER2, and Basal-like (triple negative)
[10] https://www.breastcancer.org/types/molecular-subtypes
[11] 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
[12] Hartkopf et al. Endocrine-Resistant Breast Cancer: Mechanisms and Treatment. Breast Care (2020) 15: 347-54
[13] Brett et al. ESR1 mutation as an emerging clinical biomarker in metastatic hormone receptor-positive breast cancer. Breast Cancer Res. (2021) 23: 85
[14] Hernando 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
[15] Ferro et al. Oral selective estrogen receptor degraders (SERDs): The new emperors in breast cancer clinical practice? Semin Oncol (2023) 26: S0093
[16] 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
[17] 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
[18] Miricescu et al. PI3K/AKT/mTOR Signaling Pathway in Breast Cancer: From Molecular Landscape to Clinical Aspects. Int J Mol Sci (2020) 22: 173
[19] Martorana et al. AKT Inhibitors: New Weapons in the Fight Against Breast Cancer? Front. Pharmacol (2021) 12: 662232
[20] Fusco et al. PIK3CA Mutations as a Molecular Target for Hormone Receptor-Positive, HER2-Negative Metastatic Breast Cancer. Front. Oncol (2021): 644737

offers tests supporting melanoma, colorectal, lung, breast and liver cancer, as well as for sepsis. More information: www.biocartis.com. Follow us on X (Twitter): @Biocartis_.

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