

Biocartis Initiates Commercialization in Europe of SkylineDx's Innovative Merlin™ Assay (CE-IVD) for Melanoma Patients

Merlin helps identify melanoma patients who may safely forgo the sentinel lymph node biopsy

- *Melanoma is the deadliest form of skin cancer¹*
- *Biocartis to initiate commercialization in Europe of SkylineDx's innovative [Merlin Assay](#), ahead of the launch of an Idylla™ version of the test*

Mechelen, Belgium, 1 September 2022 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the start of the commercialization in Europe of SkylineDx's innovative [Merlin Assay](#) as a CE-IVD marked manual kit. The test, developed by SkylineDx together with the Mayo Clinic (US), aims to predict a melanoma patient's risk of nodal metastasis and may help safely forgo an invasive surgery, which is now often performed to determine metastatic spread of the cancer for staging purposes. In approximately 80% of surgeries, the biopsy comes back negative for metastasis, where it does not further impact the patient pathway. Merlin Assay provides a more personalized insight, identifying patients with a low-risk tumor that could avoid the surgery². The Merlin Assay will be commercialized in Europe by Biocartis as a CE-IVD marked manual kit, ahead of the launch of an Idylla™ version of the test which is under development.

Biocartis and SkylineDx, a Dutch (Rotterdam) and US (San Diego, California) based private biotechnology company, announced their partnership agreement on [22 April 2021](#). Under the terms of the partnership agreement, SkylineDx is leading the development of the Merlin Assay on Idylla™, while Biocartis is leading the commercialization in Europe through its growing Idylla™ network. As part of the commercialization in Europe, Biocartis will now also commercialize the CE-IVD marked manual kit, ahead of the Idylla™ version of the Merlin Assay. In the US, the test is already available as a Laboratory Developed Test serviced from SkylineDx' CAP/CLIA laboratory. SkylineDx received Medicare reimbursement for the test in [May 2022](#).

Herman Verrelst, Chief Executive Officer of Biocartis, commented: *"We are very excited to start commercialization in Europe of SkylineDx's CE-IVD marked manual kit of the Merlin Assay. This manual kit is based on a well-established qPCR method that can easily run in molecular diagnostic laboratories. Although it's the first time we are commercializing a partner test ahead of an Idylla™ version of the test, this version of the Merlin Assay may offer our European customer base of large molecular diagnostic labs already a clear added value to help improve outcomes for melanoma patients. Once completed, the Idylla™ version of the Merlin Assay is expected to allow an even broader access for melanoma patients across Europe, with reduced time to results."*

Dharminder Chahal, Chief Executive Officer of SkylineDx, replied: *"Launching the Merlin Assay as a CE-IVD marked manual kit in Europe signifies a major milestone in making our diagnostic solutions available to patients globally. We are looking forward to enter this new phase of our partnership with Biocartis."*

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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_.

1 Source: <https://www.nccn.org/patients/guidelines/content/PDF/melanoma-patient.pdf>, last consulted on 24 August 2022

2 Bellomo et al., Model combining tumor molecular and clinicopathologic risk factors predicts sentinel lymph node metastasis in primary cutaneous melanoma. JCO Precision Oncology (2020). <https://doi.org/10.1200/PO.19.00206>.

About SkylineDx

SkylineDx is a biotechnology company focused on research & development of molecular diagnostics in oncology and inflammatory diseases. The company is headquartered in Rotterdam (the Netherlands) and complemented with a commercial team, a field medical and scientific affairs team and a CAP/CLIA certified laboratory in San Diego (CA, USA). SkylineDx uses its expertise to bridge the gap between academically discovered gene expression signatures and commercially available diagnostic products with high clinical utility, assisting healthcare professionals in accurately determining the type or status of disease or predicting a patient's response to treatment. Based on test results, healthcare professionals can tailor the treatment approach to the individual patient. To learn more about SkylineDx, please visit www.skylinedx.com.

About Merlin Assay

Merlin Assay uses the CP-GEP model, a powerful proprietary algorithm that calculates the risk of metastasis in a patient's sentinel lymph nodes³. The model is able to calculate risk on an individual basis through a combination analysis of eight genes from the patient's primary tumor, the tumor thickness and the patient's age; and has been analytically and clinically validated. Further clinical research and validation studies on the predictive use of the CP-GEP model is the main focus of Merlin Study Initiative, developed under the wings of Falcon R&D Program. More information (including references) may be obtained at www.falconprogram.com. Its US counterpart Merlin Test is commercially available and Medicare reimbursed in the United States as a Laboratory Developed Test serviced from SkylineDx's CAP/CLIA laboratory in San Diego (CA).

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³ Bellomo et al., Model combining tumor molecular and clinicopathologic risk factors predicts sentinel lymph node metastasis in primary cutaneous melanoma. JCO Precision Oncology (2020). <https://doi.org/10.1200/PO.19.00206>