



PRESS RELEASE

REGULATED-INSIDE INFORMATION

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Biocartis and SkylineDx Sign Collaboration to Develop the Merlin Assay, a Test Predicting Risk for Nodal Metastasis in Melanoma, on Idylla™

Mechelen, Belgium, 22 April 2021 - Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), and [SkylineDx](#), a Dutch (Rotterdam) and US (San Diego, California) based private biotechnology company focused on research & development of molecular diagnostics in oncology and inflammatory diseases, today announce the signing of a new partnership agreement which targets the development of SkylineDx' novel proprietary test, the Merlin Assay, on Biocartis' rapid and easy-to-use molecular diagnostics platform Idylla™. This assay is aimed at predicting a patient's risk of nodal metastasis in melanoma. Under the terms of the partnership agreement, SkylineDx will lead the development of the Merlin Assay on Idylla™, while Biocartis will lead the commercialization in Europe through its growing Idylla™ network.

Melanoma is the deadliest form of skin cancer¹ and incidence rates are substantial in Europe with approx. 144k cases/year², in the US with approx. 100k cases/year³ and in Australia with approx. 16,000 cases/year⁴. When diagnosed, prognosis and treatment decisions depend on disease staging⁵. Current staging methods include performing an SLN (sentinel lymph node) biopsy⁶, which is an invasive surgical intervention under general anesthesia, carrying a >10% risk of complications⁷. Moreover, 80-85% of SLN biopsies appear unnecessary as no nodal metastases are found⁸.

The Merlin Assay aims to reduce the number of unnecessary SLN surgeries through the combination of gene expression (from the primary melanoma) with the patient's age and tumor thickness, allowing the identification of patients at low risk of nodal metastasis⁸. As such, the Idylla™ Merlin Assay would provide a rapid and easy-to-use tool for physicians to identify patients who may safely forgo the SLN biopsy procedure.

Today, the Merlin Assay is already available as a Laboratory Developed Test in SkylineDx' CAP/CLIA laboratory in San Diego (California, US). For Europe, a molecular subtyping test kit for *in vitro* diagnostic use, mainly addressing centralized expert laboratories is under development and will be commercialized by Biocartis ahead of the Idylla™ version of the assay. Building on Idylla™'s decentralization capabilities, the Idylla™ version of the Merlin Assay will allow improved access for patients across Europe while reducing time to results.

Herman Verrelst, Chief Executive Officer of Biocartis, commented: *"We are excited about teaming up with SkylineDx to improve melanoma patient outcome and help clinicians, also in smaller, non-specialized lab settings, to rapidly and easily guide the true need for surgical removal of lymph nodes in melanoma patients. This Idylla™ Merlin Assay also connects well with our current oncology offering, where the Idylla™ BRAF Mutation Test (CE-IVD)⁹ can subsequently help to guide a patient's treatment decisions in cases of metastatic melanoma."*

Dharminder Chahal, Chief Executive Officer of SkylineDx, added: *"Through this collaboration with Biocartis, we enable a broader availability of our test portfolio in melanoma. SkylineDx focuses on precision diagnostics for all cancer patients and with the addition of this new version of our Merlin Assay, more laboratories and care settings will be able to have access to this assay. Our teams are fully up to speed and we really look forward to start the development process together"*.

As part of the agreement and based on SkylineDx' highly valuable portfolio of novel molecular tests in varying stages of development and expected attractive value-based pricing, Biocartis will invest up to EUR 10m in secured convertible notes to be issued by SkylineDx in different project-based instalments throughout the collaboration. The initiation of the development of the Merlin Assay on Idylla™ is expected to start in 2021.

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1 Source: <https://www.nccn.org/patients/guidelines/content/PDF/melanoma-patient.pdf>, last consulted on 20 April 2021

2 Source: <http://www.melanomapatientnetwork.eu.org/melanoma.html>, last consulted on 20 April 2021

3 National US Cancer Institute, <https://seer.cancer.gov/statfacts/html/melan.html>, last consulted on 20 April 2021

4 Source: Cancer Australia, <https://www.cancer australia.gov.au/affected-cancer/cancer-types/melanoma/melanoma-skin-statistics>, last consulted on 20 April 2021

5 Crucial in determining disease stage is metastatic spread of cancerous cells to the sentinel lymph nodes (SLN)

6 A sentinel lymph node biopsy (SLNB) is a surgical procedure used to determine whether cancer has spread beyond a primary tumor into the lymphatic system. Source: Mayo Clinic, <https://www.mayoclinic.org/tests-procedures/sentinel-node-biopsy/about/pac-20385264>, last consulted on 20 April 2021

7 Ascha M, et al. Ann Plast Surg 79:509-515, 2017, https://journals.lww.com/annalsplasticsurgery/Abstract/2017/11000/Identification_of_Risk_Factors_in_Lymphatic.22.aspx

8 Bellomo et al. JCO Precision Oncology, <https://ascopubs.org/doi/10.1200/PO.19.00206>

9 The Idylla™ BRAF Mutation Test, performed on the Idylla™ platform, is an in vitro diagnostic Test for the qualitative detection of V600E/E2/D and V600K/R/M mutations in codon 600 of the BRAF gene. The Idylla™ BRAF Mutation Test, from sample-to-result, starts with formalin-fixed paraffin-embedded (FFPE) human tissue from metastatic melanoma to liberate DNA for subsequent real-time PCR amplification and detection

More information:

Biocartis

Renate Degraeve, Head of Corporate Communications & Investor Relations Biocartis

e-mail rdegrave@biocartis.com

tel +32 15 631 729

mobile +32 471 53 60 64

 [@Biocartis](https://twitter.com/Biocartis)  www.linkedin.com/Biocartis

SkylineDx

Marieke Spaan, Manager Corporate Affairs SkylineDx

e-mail m.spaan@skylinedx.com

tel +31 10 72 00 310

mobile +31 6 42 66 51 73

 [@skylinedx](https://twitter.com/skylinedx)  <https://www.linkedin.com/company/skylinedx-bv>

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 SARS-CoV-2 and sepsis. More information: www.biocartis.com. Follow us on [Twitter](https://twitter.com/Biocartis_): @Biocartis_.

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 field medical and scientific affairs team in the US and a CAP/CLIA certified laboratory in San Diego (California). 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 predict a patient's response to treatment. Based on test results, healthcare professionals can tailor the treatment approach to the individual patient. To learn more on SkylineDx, please visit www.skylinedx.com. To learn more on the Merlin Assay and the overarching Falcon Melanoma R&D Program, please visit www.falconprogram.com.

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