

## Biocartis Announces Presentation of First Prospective Validation Study Data of Merlin Test by Partner SkylineDx at EADO 2022 Conference

**Mechelen, Belgium, 21 April 2022** – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announced that its partner [SkylineDx](#) will present new data showing that its Merlin Test was able to prospectively reduce more than 37% of surgeries in a non-interventional study for newly diagnosed melanoma patients<sup>1</sup>. The abstract publication receives a designated oral presentation during the 18<sup>th</sup> Congress of the European Association of Dermato-oncology (EADO) in Sevilla, Spain (21-23 April 2022).

The Merlin Test identifies melanoma patients that have a low risk for nodal metastasis and therefore can safely forgo a sentinel lymph node biopsy (SLNB) surgery. This is an invasive surgical procedure used to determine metastatic spread of the cancer for staging purposes. In approximately 80% of the surgeries, the biopsy comes back negative for metastasis and does not further impact the patient pathway. The Merlin Test provides a more personalized insight on the metastatic propensity of the tumor, and how patients with a low-risk tumor could avoid the surgery<sup>2</sup>.

Four melanoma medical centers from the Netherlands are leading this prospective multicenter study which is currently still ongoing. The study was initiated during the first wave of the COVID-19 pandemic to allow for surgical triage on SLNB and to evaluate the implementation of the Merlin Test in clinical practice. Results of this prospective trial confirm the performance of previously published European and US retrospective validation studies in real world practice.

On 22 April 2021, Biocartis and SkylineDx [announced](#) a partnership aimed at developing SkylineDx' novel proprietary test, the Merlin Test, on Biocartis' rapid and easy-to-use molecular diagnostics platform Idylla™. In the US, the Merlin Test is already available as an internal Laboratory Developed Test in SkylineDx' CAP/CLIA laboratory in San Diego (California, US). Under the terms of the partnership agreement, SkylineDx will lead the development of the Merlin Test on Idylla™, while Biocartis will lead the commercialization in Europe through its growing Idylla™ network. Ahead of the launch of the Merlin Test on Idylla™, Biocartis will already commercialize the test kit version of the Merlin Test for in vitro diagnostic use in Europe.

**Herman Verrelst, Chief Executive Officer of Biocartis, commented:** *"Presenting this new prospective data at the EADO conference is a great way to initiate our joint commercial activities with SkylineDx, addressing mainly centralized expert laboratories in Europe."*

*"EADO 2022 will be the first European conference that we attend together with our collaboration partner Biocartis", comments Dharminder Chahal, CEO SkylineDx. "It is exciting that in our first collective outreach we are able to show new prospective data that further strengthens the scientific solidity and clinical relevance of our Merlin Test"*.

The commercial launch of the test kit version of the Merlin Test for in vitro diagnostic use in Europe is planned in the second half of 2022.

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<sup>1</sup> Stassen R.C. et al, 'Use of CP-GEP to identify primary cutaneous melanoma patients with a low risk for SN metastasis in a prospective multicenter Dutch study during COVID-19', first presented at EADO 2022, 21-23 April 2022 (Seville, Spain). Find the link [here](#)  
<sup>2</sup> Bellomo et al., Model combining tumor molecular and clinicopathologic risk factors predicts sentinel lymph node metastasis in primary cutaneous melanoma. JCO Precision Oncology (2020).

## **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](http://www.biocartis.com). Follow us on [Twitter](https://twitter.com/Biocartis_): @Biocartis\_.

## **About the Merlin Test**

The Merlin Test uses the CP-GEP model, a powerful algorithm that calculates the risk of metastasis in a patient's sentinel lymph nodes. The model is able to calculate risk on an individual basis through a combination analysis of 8 genes from the patient's primary tumor, the tumor thickness and the patient's age; and has been independently validated in several cohorts. Further clinical research and validation studies on the predictive use of the CP-GEP model is the main focus of the Merlin Study Initiative, developed under the wings of the Falcon R&D Program. More information (including references) on [www.falconprogram.com](http://www.falconprogram.com).

## **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 USA 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. More information about SkylineDx on [www.skylinedx.com](http://www.skylinedx.com).

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### **Forward-looking statements**

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