

BIOCARTIS HOLDINGS INC.

PRESS RELEASE

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RECAPITALIZATION COMPLETED AND PRODUCT PORTFOLIO EXPANSION

- *The recapitalization of Biocartis was completed last week, strengthening the balance sheet with a new investment of €40 million and a €132 million conversion of debt to equity.*
- *Product portfolio expansion with the launch of three breast cancer products: the Idylla™ PIK3CA-AKT1 Mutation Assay and, in collaboration with our partner APIS, the APIS Breast Cancer Subtyping Kit and the APIS ESR1 Mutations Kit.*
- *Upcoming launches of thyroid and melanoma partner assays planned in Q4 2023.*

Mechelen, Belgium, and Itasca (IL) United States 22 November 2023 – Biocartis Holdings Inc., the entity that now owns Biocartis NV and Biocartis US Inc., announces that its balance sheet recapitalization is complete. As part of this recapitalization plan, the balance sheet is substantially strengthened with the prior secured creditors of Biocartis Group NV, converting a significant proportion of debt into equity in Biocartis Holdings Inc.

In connection with the restructuring, approximately €132 million of debt was converted into equity, with the new lead shareholders of Biocartis Holdings Inc. also investing an additional €40 million of new cash. As previously announced, customers, suppliers, partners, employees and trade creditors of Biocartis NV and Biocartis US Inc. have not been impacted by the change in ownership of the Biocartis business.

Biocartis has also expanded its product portfolio with the launch of the **Idylla™ PIK3CA-AKT1 Mutation Assay** (RUO¹). PIK3CA is an important biomarker in the treatment of advanced breast cancer and research shows that it plays a key role in other cancer indications as well.² Through Biocartis' partnership with APIS Assay Technologies, it simultaneously co-launched the **APIS Breast Cancer Subtyping Kit** (RUO) and the **APIS ESR1 Mutations Kit** (RUO). The APIS Breast Cancer Subtyping Kit is an advanced assay for characterizing³ early stage breast cancer in less than five hours, while the APIS ESR1 Mutations Kit supports detection of mutations in the estrogen receptor gene (ESR1) that are associated with resistance to endocrine therapy⁴.

Biocartis is planning more product launches with its partners this year: **Idylla™ CP-GEP** (RUO) and the **Idylla™ ThyroidPrint® Assay** (RUO). Idylla™ CP-GEP is developed in partnership with SkylineDx and is based on a powerful proprietary algorithm that combines clinicopathological (CP) factors with gene expression profiling (GEP) information obtained from cutaneous melanoma FFPE⁵ samples. This product enables laboratories to conduct further research in cutaneous melanoma. The Idylla™ ThyroidPrint® Assay is an advanced genomic signature Assay that is developed in collaboration with GeneproDX. This product measures a gene expression signature from FNA⁶ samples and enables laboratories to conduct further research on risk stratification of indeterminate thyroid nodules.

Roger Moody, Chief Executive Officer of Biocartis, commented: *"We are very pleased to have the recapitalization behind us. The new funding will, in combination with the significantly lowered cost structure and debt structure, allow Biocartis to invest in expanding its business instead of servicing its debt. Having completed the recapitalization, we have the foundation for a bright future. We are also very excited about our expanding product portfolio. The new oncology tests that we have recently launched should help our growth in 2024 and beyond, as we continue to deliver faster testing solutions to our customers. In addition, we look forward to continuing to expand our product portfolio with tests in the field of cutaneous melanoma and thyroid cancer. Oncologists are looking for faster results to get cancer patients on the right treatment, and our Idylla™ Platform is the ideal solution to these market needs. We continue to work hard towards the goal for our products to make a difference for cancer patients around the world."*

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¹ For Research Use Only (RUO), not for use in diagnostic procedures.

² Miricescu et al. PI3K/AKT/mTOR Signaling Pathway in Breast Cancer: From Molecular Landscape to Clinical Aspects. Int J Mol Sci (2020) 22: 173

³ 13th St. Gallen International Breast Cancer Conference 2013, Expert panel consensus opinion.

⁴ Brett et al. ESR1 mutation as an emerging clinical biomarker in metastatic hormone receptor-positive breast cancer. Breast Cancer Res. (2021) 23: 85

⁵ Formalin-Fixed Paraffin-Embedded

⁶ Fine Needle Aspiration

More information:

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About Biocartis

With its revolutionary and proprietary Idylla™ Platform, Biocartis 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 addresses 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, breast and liver cancer, as well as for sepsis. More information: www.biocartis.com. Follow us on [X \(Twitter\)](#): @Biocartis_.

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