

## Biocartis and Ophiomics to Collaborate on Liver Cancer Test

- Primary liver cancer<sup>1</sup> is the sixth most common and third most lethal cancer in the world
- Collaboration to focus on commercialization of HepatoPredict™, a prognostic gene expression signature test to identify which patients will benefit from liver transplantation

**Mechelen, Belgium, 8 February 2022** - Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), and Ophiomics, a Lisbon (Portugal) based biotech company developing a precision medicine portfolio focused on liver cancer, today announce that they entered into a collaboration which will initially focus on the commercialization of [HepatoPredict™](#), a prognostic gene expression signature test to help identify which patients will benefit from curative-intent surgery, in particular liver transplantation. HepatoPredict™ will be distributed by Biocartis in Europe as a manual kit mainly addressing centralized expert laboratories, and the test may later be translated into a version on Biocartis' rapid and easy-to-use molecular diagnostics platform Idylla™.

Primary liver cancer is the sixth most common and third most lethal cancer in the world, with more than 900,000 new cases per year resulting in more than 800,000 deaths per year<sup>2</sup>. Hepatocellular carcinoma (HCC) is the most common type of primary liver cancer that frequently occurs in people with chronic liver diseases, such as cirrhosis<sup>3</sup>. Treatment options include ablation<sup>4</sup>, surgical resection<sup>5</sup> or transplantation, with liver transplant being the most effective curative treatment for HCC patients with cirrhosis<sup>6</sup>. Due to shortage of donor organs, the proper selection of patients is crucial. Current models to select patients are sub-optimal<sup>7</sup>, leading to potential exclusion of patients that may benefit from surgery.

HepatoPredict™ is a gene expression signature test that combines clinical parameters with molecular markers to assess the tumor biology, aiming to predict which patients will benefit most from liver transplant and identifying those for which a transplant should be avoided. HepatoPredict™ has been validated retrospectively with encouraging results, increasing the number of patients that can benefit from curative-intent transplantation by 32%<sup>8</sup>. Further prospective and retrospective validation is ongoing<sup>9</sup>.

HepatoPredict™ will be launched as a CE-marked IVD manual kit in Q1 2022. The partnership will initially focus on Biocartis' commercialization of the manual kit in Europe. In a next stage, depending on successful commercial uptake of the manual kit, Ophiomics and Biocartis aim to initiate the development of a fully automated version of the test on Biocartis' decentralized Idylla™ platform.

**Herman Verrelst, Chief Executive Officer of Biocartis, commented:** "We are excited to partner with Ophiomics to improve outcomes for liver cancer patients. The availability of a manual kit version of the Ophiomics test allows us to help patients and generate commercial traction right from the start of the collaboration while we prepare to bring this test onto our Idylla™ platform to maximize patient access to the test long term."

**José Pereira Leal, Chief Executive Officer of Ophiomics, added:** "We are thrilled to be initiating this collaboration with a company that is complementary to Ophiomics' vision to develop effective precision medicine solutions that enable patients and healthcare providers to make the best treatment decisions. This partnership will enable us to immediately leverage Biocartis' commercial organization for an early access to the European market, anticipating future, closer collaboration on this and other assays."

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<sup>1</sup> Primary liver cancer is a cancer that starts in the liver, in contrast to secondary liver cancer where the liver tumors are the result of metastasis from a primary tumor elsewhere in the patient

<sup>2</sup> Source: Globocan 2020

<sup>3</sup> Cirrhosis is a late-stage liver disease that is characterized by fibrosis (scarring) of the liver tissue. Main causes include alcoholic liver disease (resulting from long term alcohol overconsumption), non-alcoholic steatohepatitis (NASH; linked to obesity and type 2 diabetes) and chronic hepatitis B or hepatitis C infection

<sup>4</sup> Ablation removes or destroys diseased tissue, for instance by using high temperature treatment

<sup>5</sup> In a partial hepatectomy the diseased section of the liver is removed. The remaining part of the liver may regrow, although with a reduced liver function

<sup>6</sup> Dhir M, Melin AA, Douailler J, et al. A Review and Update of Treatment Options and Controversies in the Management of Hepatocellular Carcinoma. *Annals of Surgery*. 2016;263:1112–1125

<sup>7</sup> Currently used selection models rely on clinical morphological models (e.g. Milan criteria: Mazzaferro et al., *N Engl J Med* (1996) 334:693-700 or San Francisco criteria: Yao et al., *Hepatology* (2001) 33:1394-40)

<sup>8</sup> Over Milan criteria, with a disease-free survival rate of 89%, or 94% when used in highest precision model. Source: Pinto-Marques et al. Submitted for publication. HepatoPredict improves current expanded selection models with precisions ranging between 53% and 84,5% while providing a clear, reproducible, objective prognosis in a few days. Source: Pavel M-C, Fuster J. Expansion of the hepatocellular carcinoma Milan criteria in liver transplantation: Future directions. *WJG*. 2018;24:3626–3636

<sup>9</sup> ClinicalTrials.gov identifier: NCT04499833

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

**About Ophiomics**

Ophiomics is a biotech company developing new products and services integrating machine learning and genomics in support of diagnostic, prognostic, pharmacogenomics, and clinical follow up in liver cancer. Ophiomics is based in Lisbon, Portugal, at the LISPOLIS incubator, close to multiple small and large companies focusing on human health technologies. Ophiomics was founded and is managed by José Leal and Joana Vaz, specialists in Bioinformatics and in Genomics, respectively. They have worked together for close to a decade, as academic researchers, establishing a clinical services laboratory focusing on oncogenomics, and now developing the next generation of products that will disrupt the way we manage liver cancer. More information: [www.ophiomics.com](http://www.ophiomics.com).

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