



PRESS RELEASE

10 October 2022, 07:00 CEST

Biocartis Initiates Commercialization in Europe of HepatoPredict (CE-IVD) Test for Liver Cancer Patients

HepatoPredict helps identify Hepatocellular Carcinoma (HCC) patients that will benefit from a liver transplantation

- Primary liver cancer¹ is the sixth most common and third most lethal cancer in the world²
- Biocartis to initiate commercialization in Europe of HepatoPredict, a prognostic gene expression signature test developed by its partner Ophiomics, to identify which liver cancer patients with Hepatocellular Carcinoma (HCC) will benefit from liver transplantation

Mechelen, Belgium, 10 October 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 the [HepatoPredict](#) test as a CE-IVD marked manual kit. The test, developed by [Ophiomics](#), is a prognostic diagnostic test that supports the decision of liver transplantation in patients with Hepatocellular Carcinoma (HCC).

Herman Verrelst, Chief Executive Officer of Biocartis, commented: "We are very excited to initiate commercialization of HepatoPredict in Europe. Thanks to our well-established European base of customer-labs, together with Ophiomics, we will now also be able to support liver cancer patients who may benefit from having a liver transplant."

José Pereira Leal, Chief Executive Officer of Ophiomics, added: "Accurately identifying which HCC patients will benefit the most from a liver transplant enables better organ allocation and waiting lists management. Launching HepatoPredict through Biocartis' network of European customers is a great next step in our collaboration to enable patients and healthcare providers to make the best treatment decisions."

On [8 February 2022](#), Biocartis and Ophiomics (a Lisbon, Portugal based biotech company developing a precision medicine portfolio focused on liver cancer) announced their partnership agreement. Under the terms of this agreement, Biocartis leads the commercialization of the manual HepatoPredict kit in Europe. Depending on the successful commercial uptake of the kit, Ophiomics and Biocartis aim to initiate the development of a fully automated version of the test on Biocartis' decentralized Idylla™ platform.

Primary liver cancer is the sixth most common and third most lethal cancer in the world, with than 900,000 new cases per year and resulting in more than 800,000 deaths per year². HCC is the most common type of primary liver cancer that frequently occurs in people with chronic liver diseases, such as cirrhosis³. Liver transplantation is the best curative treatment for HCC patients. The current criteria used to identify patients for transplantation are either too strict (by rejecting patients that could benefit from the transplant) or overestimate the benefit from a liver transplantation (by selecting patients that will relapse afterwards).

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 a liver transplant and identifying those for which a transplant brings no benefit. HepatoPredict has been validated retrospectively with encouraging results, increasing the number of patients that can benefit from curative-intent transplantation by 31%⁴. The first clinical validation of HepatoPredict was published on 29 August 2022 in 'Annals of Surgery' in a collaborative retrospective study⁵ with Curry Cabral Hospital (Lisbon, Portugal). The study showed that HepatoPredict outperforms conventional selection criteria⁶, as such providing superior information to identify patients that are most likely to benefit from a liver transplant.

More information on the test can be found on the Biocartis website [here](#).

--- END ---

More information:

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](#) www.linkedin.com/Biocartis

¹ Primary liver cancer is a cancer that starts in the liver, in contrast to secondary liver cancer where the liver tumour is the result of metastasis from a primary tumor elsewhere in the patient

² Source: Globocan 2020

³ 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

⁴ Over Milan criteria, with a disease-free survival rate of 89%, or 94% when used in highest precision model. Source: Pinto-Marques H, Cardoso J, Silva S, Neto JL, Gonçalves-Reis M, Proença D, Mesquita M, Manso A, Carapeta S, Sobral M, Figueiredo A, Rodrigues C, Milheiro A, Carvalho A, Perdigo R, Barroso E, Pereira-Leal JB. A Gene Expression Signature to Select Hepatocellular Carcinoma Patients for Liver Transplantation. *Ann Surg.* 2022 Aug 1. doi: 10.1097/SLA.0000000000005637. Epub ahead of print. PMID: 35916378. 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

⁵ Pinto-Marques H, Cardoso J, Silva S, Neto JL, Gonçalves-Reis M, Proença D, Mesquita M, Manso A, Carapeta S, Sobral M, Figueiredo A, Rodrigues C, Milheiro A, Carvalho A, Perdigo R, Barroso E, Pereira-Leal JB. A Gene Expression Signature to Select Hepatocellular Carcinoma Patients for Liver Transplantation. *Ann Surg.* 2022 Aug 1. doi: 10.1097/SLA.0000000000005637. Epub ahead of print. PMID: 35916378

⁶ Such as Milan and UCSF. In order to identify a patient for liver transplant, different sets of criteria such as the Milan or the UCSF (University of California San Francisco) criteria are used

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, lung and liver cancer, as well as for COVID-19, Flu, RSV and sepsis. More information: 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.

About HepatoPredict

HepatoPredict is a prognostic tool supporting the decision of liver transplantation in HCC. A molecular signature is integrated with clinical parameters into a predictive algorithm that estimates the risk of HCC recurrence after a liver transplant. It is based on a gene expression signature, measured by a real-time PCR assay, of four target genes and three housekeeping genes, and clinical parameters combined into a computational algorithm, that can predict the good outcome of the intervention with a successful-curative rate up to 94%. The test is performed on HCC biopsies and is intended to be exclusively used on RNA samples extracted from formalin-fixed paraffin-embedded (FFPE) HCC tissue and should be only used with the provided reagents and software. More information: www.ophiomics.com/hepatopredict.

Biocartis and Idylla™ are registered trademarks in Europe, the United States and other countries. The Biocartis and Idylla™ trademark and logo are used trademarks owned by Biocartis. Please refer to the product labeling for applicable intended uses for each individual Biocartis product.

This press release is not for distribution, directly or indirectly, in any jurisdiction where to do so would be unlawful. Any persons reading this press release should inform themselves of and observe any such restrictions. Biocartis takes no responsibility for any violation of any such restrictions by any person. This press release does not constitute an offer or invitation for the sale or purchase of securities in any jurisdiction. No securities of Biocartis may be offered or sold in the United States of America absent registration with the United States Securities and Exchange Commission or an exemption from registration under the U.S. Securities Act of 1933, as amended.

Forward-looking statements

Certain statements, beliefs and opinions in this press release are forward-looking, which reflect the Company's or, as appropriate, the Company directors' or managements' current expectations and projections concerning future events such as the Company's results of operations, financial condition, liquidity, performance, prospects, growth, strategies and the industry in which the Company operates. By their nature, forward-looking statements involve a number of risks, uncertainties, assumptions and other factors that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties, assumptions and factors could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward-looking statements contained in this press release regarding past trends or activities are not guarantees of future performance and should not be taken as a representation that such trends or activities will continue in the future. In addition, even if actual results or developments are consistent with the forward-looking statements contained in this press release, those results or developments may not be indicative of results or developments in future periods. No representations and warranties are made as to the accuracy or fairness of such forward-looking statements. As a result, the Company expressly disclaims any obligation or undertaking to release any updates or revisions to any forward-looking statements in this press release as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based, except if specifically required to do so by law or regulation. Neither the Company nor its advisers or representatives nor any of its subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this press release or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this press release.