

PRESS RELEASE

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# Genomic Health and Biocartis Announce Agreement to Develop an Idylla™ IVD Oncotype DX<sup>®</sup> Breast Cancer Test to Broaden Global Patient Access

Strategic Collaboration Aimed at Exclusive Test Development and Commercialization of Proprietary Genomic Health Tests on the Idylla™ Platform

**REDWOOD CITY, Calif., United States, and MECHELEN, Belgium, September 13, 2017** -- Genomic Health, Inc., the world's leading provider of genomic-based diagnostic tests (NASDAQ: GHDX) and Biocartis Group NV, an innovative molecular diagnostics company (Euronext Brussels: BCART), today announced an exclusive agreement to develop an IVD version of the Oncotype DX Breast Recurrence Score® test on Biocartis' Idylla™ platform that can be performed locally by laboratory partners and in hospitals around the world.

The Oncotype DX Breast Recurrence Score test examines the activity of 21 genes in a patient's breast tumor tissue to provide personalized information for tailoring treatment based on the biology of their individual disease. As the only test proven to predict chemotherapy benefit, the Oncotype DX Breast Recurrence Score test is included in all major cancer guidelines worldwide and is now considered standard of care for early-stage breast cancer.

Biocartis' proprietary Idylla<sup>TM</sup> platform offers a unique solution that is currently unmatched in the localization of complex molecular diagnostics. With the fully automated sample-to-answer, real-time PCR¹-based cartridge of the Idylla platform, Genomic Health intends to enable local pathology labs to generate Oncotype DX Breast Recurrence Score results with minimal labor, efficient turnaround time, and the consistent high quality and clinical utility that physicians and patients have come to expect when making treatment decisions with Oncotype DX.

"We are excited to augment our successful U.S. centralized laboratory business model with an IVD system that can be implemented by local laboratories to increase global patient access to standard of care testing with the Oncotype DX Breast Recurrence Score test planned for launch in Europe beginning with France and Germany in 2019," said Frederic Pla, Ph.D., chief business and product development officer, Genomic Health. "We believe our strategic collaboration with Biocartis positions us to accelerate adoption and market access around the world, as well as to broaden partnership opportunities with pharmaceutical companies seeking diagnostic solutions with the ability to develop and offer tests globally through decentralized settings."

Herman Verrelst, chief executive officer of Biocartis, commented: "Adding world-leading assays such as the Oncotype DX test to our Idylla platform is an essential step in our strategy to rapidly expand the menu offering on our platform. Today's announcement demonstrates how we can assist providers of proprietary molecular tests in making their offering available to local labs across the globe, without the need for a highly specialized molecular diagnostics infrastructure. This demonstrates the true strength and ambition of the Idylla™ technology: enabling the

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<sup>&</sup>lt;sup>1</sup> Polymerase Chain Reaction

best molecular diagnostics for all patients, worldwide. We are impressed by what Genomic Health has realized so far and our team looks forward to making this strategic collaboration a success."

The strategic collaboration will provide Genomic Health with exclusive worldwide rights to develop and commercialize its Oncotype DX Breast Recurrence  $Score^{\$}$  test on the Idylla<sup>TM</sup> platform, with the option to expand the collaboration to include additional tests in oncology and urology. Development of the Oncotype DX $^{\$}$  IVD test is expected to begin in late 2017, with the aim of providing initial access to patients in Europe, beginning with France and Germany, in 2019.

As part of the agreement, Genomic Health will make a payment of approximately \$3.3 million to Biocartis, which is expected to be expensed in the third quarter of 2017. Additional payments to Biocartis will be made as certain developmental and commercial milestones are achieved in the future. Genomic Health continues to expect to be profitable for the full year 2017, excluding these transaction costs. Upon commercialization, Genomic Health will make royalty payments to Biocartis based on net sales of the IVD tests developed on Biocartis' Idylla<sup>TM</sup> platform.

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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 launched the Idylla™ platform end 2014. Biocartis is developing and marketing a rapidly expanding test menu addressing key unmet clinical needs in oncology and infectious diseases. These areas represent respectively the fastest growing and largest segments of the MDx market worldwide. Today, Biocartis offers ten oncology tests and two infectious disease tests in Europe. More information: www.biocartis.com. Press Photo Library available here. Follow us on Twitter: @Biocartis\_.

# **About Genomic Health**

Genomic Health, Inc. (NASDAQ: GHDX) is the world's leading provider of genomic-based diagnostic tests that help optimize cancer care, including addressing the overtreatment of the disease, one of the greatest issues in healthcare today. With its Oncotype IO<sup>®</sup> Genomic Intelligence Platform, the company is applying its world-class scientific and commercial expertise and infrastructure to lead the translation of clinical and genomic big data into actionable results for treatment planning throughout the cancer patient journey, from diagnosis to treatment selection and monitoring. The Oncotype IQ portfolio of genomic tests and services currently consists of the company's flagship line of Oncotype DX® gene expression tests that have been used to guide treatment decisions for more than 800,000 cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid- and tissue-based tests, including the recently launched Oncotype SEQ® Liquid Select™ test. The company is based in Redwood <u>City</u>, California, with international headquarters in Geneva, Switzerland. For more information, please visit, www.GenomicHealth.com and follow the company on

twitter: @GenomicHealth, Facebook, YouTube and LinkedIn.

# **Biocartis Forward-Looking Statements**

Certain statements, beliefs and opinions in this press release are forward-looking, which reflect Biocartis' or, as appropriate, Biocartis' directors' or managements' current expectations and projections concerning future events such as Biocartis' results of operations, financial condition, liquidity, performance, prospects, growth, strategies and the industry in which Biocartis 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. As a result, Biocartis 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. Neither Biocartis nor its advisers or representatives nor any of its subsidiary undertakings or any such persons's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either a

# **Genomic Health Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to Genomic Health's beliefs regarding its future performance, including its guidance of profitability for the full year 2017 and the factors that may impact such guidance; the company's ability to successfully develop and commercialize an IVD test; the expected benefits of an IVD version of the company's breast cancer test, and its expectations regarding timing and geographic rollout of any such test; the company's belief that the collaboration will allow it to accelerate adoption, reimbursement and access to the test and broaden other partnership opportunities; the commercial performance of its tests; the attributes and focus of the company's product pipeline; the ability of any potential tests the company may develop to optimize cancer treatment; and the ability of the company to develop and commercialize, and collaborate with third parties to commercialize, additional tests in the future. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially, and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to Genomic Health's ability to execute its business model; the regulation of Genomic Health's tests or any tests offered through its commercial channel; the applicability of clinical study results to actual outcomes; Genomic Health's ability to develop, commercialize or collaborate to offer any new test, including an IVD version of its breast cancer test, in new markets domestically and internationally; the risk that sufficient levels of reimbursement may not be obtained or maintained, domestically or abroad, for Genomic Health's tests or tests offered through its commercial channel; competition; unanticipated costs or delays in research and development efforts; Genomic Health's ability or the ability of its collaborators to obtain capital when needed to support the activities contemplated by the collaboration described in this press release; and the other risks and uncertainties set forth in Genomic Health's filings with the Securities and Exchange Commission, including the risks set forth in Genomic Health's Quarterly Report on Form 10-Q for the quarter ended June 30, 2017. These forward-looking statements speak only as of the date hereof. Genomic Health disclaims any obligation to update these forward-looking statements.

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