



PRESS RELEASE

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# Genomic Health and Biocartis Expand Collaboration to Urology with the Development of an Idylla™ Oncotype DX Genomic Prostate Score® Test

**REDWOOD CITY, Calif., United States, and MECHELEN, Belgium, 3 December 2018** – 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 announce they have expanded their exclusive collaboration into the field of urology with the development of an in vitro diagnostic (IVD) version of the Oncotype DX Genomic Prostate Score® (GPS $^{\text{TM}}$ ) Test on Biocartis' Idylla $^{\text{TM}}$  platform and potentially additional cancer tests that can be performed locally by laboratory partners and in hospitals around the world.

Although prostate cancer is the most common cancer among men, it can fortunately often be treated successfully<sup>1</sup>. The Oncotype DX GPS test is the only commercially available tissue biopsy-based, multi-gene test that has been clinically validated to assess the aggressiveness of prostate cancer in men with clinically low-risk or favorable intermediate-risk cancer at the time of diagnosis, helping to make better informed and more personalized treatment decisions<sup>2</sup>. Today, this test has been validated in more than 4,500 patients, which is described in 18 publications<sup>3</sup>.

The Idylla™ Oncotype DX GPS Test will be the first urology test to be developed on Biocartis' fully automated PCR⁴-based Idylla™ platform, which offers a unique sample-to-result molecular diagnostics solution. Through this development, Genomic Health intends to enable local pathology labs and urology centers to generate accurate Oncotype DX GPS test results with 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.

**Herman Verrelst, Chief Executive Officer of Biocartis, commented**: "I am very happy to announce the expansion of our collaboration with Genomic Health, with whom we are now entering the domain of urological cancer testing which is a promising new market for Idylla $^{\text{TM}}$ . Once available, the Idylla $^{\text{TM}}$  Oncotype DX GPS test can support pathology labs and also local urology centers across the world in making better informed treatment decisions for patients with prostate cancer."

Frederic Pla, Ph.D., Chief Operating Officer, Genomic Health, continued: "Today's announcement follows the successful progress in our development of an IVD version of the Oncotype DX Breast Recurrence Score® test on Biocartis' Idylla<sup>TM</sup> platform that we announced last year. Expanding our collaboration to initiate development of the Oncotype DX GPS test on this fully automated sample-to-answer platform reflects our confidence in the Idylla<sup>TM</sup> platform as a best-in-class solution to accelerate access to Oncotype tests around the world."

The expanded collaboration will provide Genomic Health with exclusive worldwide rights to develop and commercialize its Oncotype DX Genomic Prostate Score test on the Idylla™ platform, with the option to expand the collaboration to

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<sup>&</sup>lt;sup>1</sup> Source: https://www.cancer.org/cancer/prostate-cancer/about.html, last consulted on 28 November 2018.

<sup>&</sup>lt;sup>2</sup> The vast majority of men currently diagnosed with low-risk prostate cancer undergo surgery or radiation treatment, although there is only a three percent chance that their disease will become life-threatening. In response to this issue, Genomic Health's tissue biopsy-based, multi-gene test has been clinically validated to predict aggressive cancer at the time of diagnosis, helping to identify those men who need immediate surgery or radiation therapy versus those who can confidently choose active surveillance. The result is a more precise and accurate assessment of risk, which helps more men avoid the lifelong complications associated with treatments they do not need, while directing aggressive therapy to those men who require immediate treatment. Source: website Genomic Health, last consulted on 28 November 2018.

<sup>3</sup> Source: website Genomic Health, last consulted on 28 November 2018.

<sup>4</sup> Polymerase Chain Reaction.

include additional tests in oncology and urology. Development of the IVD version of the GPS test is expected to begin in early 2019.

As part of the agreement, Genomic Health will make a payment of EUR 2.5 million to Biocartis, which is expected to be expensed in the fourth quarter of 2018. Upon commercialization, Genomic Health will make royalty payments to Biocartis based on net sales.

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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 in September 2014. Biocartis is developing and marketing a rapidly expanding test menu addressing key unmet clinical needs in oncology. This area represents the fastest growing segment of the MDx market worldwide. Today, Biocartis offers fifteen 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 IQ® 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 900,000 cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid- and tissue-based tests, including the recently launched Oncotype DX® AR-V7 Nucleus Detect™ test. The company is based in Redwood City, California, with international headquarters in Geneva, Switzerland. For more information, visit, www.GenomicHealth.com and follow the company on

Twitter: @GenomicHealth, Facebook, YouTube and LinkedIn.

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## Biocartis forward-looking statements

This press release may contain forward-looking statements. Such forward-looking statements are not guarantees of future performance. These forward-looking statements speak only as of the date of this press release. Biocartis expressly disclaims any obligation or undertaking to release any updates or revisions to any forward-looking statements in this press release, except if specifically required to do so by law or regulation. You should not place undue reliance on forward-looking statements.

#### 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; the company's ability to successfully develop and commercialize an in vitro diagnostic (IVD) version of the Oncotype Dx Genomic Prostate Score test on the Idylla™ platform; the expected benefits of an IVD version of the company's prostate 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 prostate 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 September 30, 2018. These forward-looking statements speak only as of the date hereof. Genomic Health disclaims any obligation to update these forward-looking statements.

NOTE: The Genomic Health logo, Oncotype, Oncotype DX, Recurrence Score, Oncotype DX AR-V7 Nucleus Detect, Oncotype DX Breast DCIS Score, Oncotype DX Genomic Prostate Score and Oncotype IQ are trademarks or registered trademarks of Genomic Health, Inc. All other trademarks and service marks are the property of their respective owners.