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Genomic Health and Almac Group Enter Exclusive In-Licensing Agreement to Develop and Commercialize Anthracycline Chemotherapy Benefit Test for High Risk Breast Cancer

REDWOOD CITY, Calif. & CRAIGAVON, Northern Ireland--(BUSINESS WIRE)-- Genomic Health, Inc. (Nasdaq: GHDX) and ALMAC GROUP Ltd jointly announced today that Genomic Health will exclusively license Almac Group's technology and intellectual property to further develop, validate and subsequently commercialize a multi-gene test to predict benefit from DNA damage-based chemotherapy drugs, such as the commonly used anthracycline-based regimens, in breast cancer. Such a test would be particularly useful for high-risk breast cancer patients who are eligible for chemotherapy based on their Oncotype DX® score.

Genomic Health will identify a study cohort for the validation of Almac's previously identified and published genes. Genomic Health made an up-front payment of \$9 million dollars, which the company expects to expense in the fourth quarter of 2013, and will pay additional milestones as certain clinical and commercial endpoints are achieved in the future. Upon successful commercialization of the test, Genomic Health will pay additional royalties to Almac Group.

"Working with Almac, we have the opportunity to gain further insight on the role of DNA repair in drug efficacy, which may provide clinical utility to help select which breast cancer patients benefit from specific chemotherapy drugs and regimens," said Steven Shak, M.D., Executive Vice President of Research and Development of Genomic Health. "Over the past ten years Oncotype DX has played a critical role in predicting benefit of chemotherapy, in general, for more than 400,000 estrogen-receptor positive breast cancer patients. This new test may address another unmet need by providing additional information specific to the benefit from anthracycline-based regimens for high-risk patients and possibly those with triple negative breast cancer as well."

Anthracycline-based chemotherapy regimens are commonly used to treat breast cancer, but have significant toxicities that can be debilitating and impact long-term quality of life. Currently, the decision to use these therapies is based on conventional clinical and pathologic factors including age, tumor grade, tumor size and patient comorbidities. However, none of these factors accurately determine which patients will benefit from anthracycline-containing regimens.

"As developers of novel prognostic and predictive tests, we are very pleased to partner with Genomic Health and look forward to leveraging their rigorous clinical validation approach and commercial expertise to advance our development work to reach patients," said Paul Harkin, President and Managing Director of Almac Diagnostics. "We see tests such as this having a significant impact on accelerating personalized healthcare thereby improving the clinical management of cancer patients."

About Genomic Health

[Genomic Health](#), Inc. (NASDAQ: [GHDX](#)) is the world's leading provider of genomic-based diagnostic tests that address both the overtreatment and optimal treatment of early stage cancer, one of the greatest issues in healthcare today. The company is applying its world-class scientific and commercial expertise and infrastructure to lead the translation of massive amounts of genomic data into clinically-actionable results for treatment planning throughout the cancer patient's journey, from screening and surveillance, through diagnosis, treatment selection and monitoring. Genomic Health's lead product, the [Oncotype DX® breast cancer test](#), has been shown to predict the likelihood of chemotherapy benefit as well as recurrence in invasive [breast cancer](#) and has been shown to predict the likelihood of recurrence in [ductal carcinoma in situ \(DCIS\)](#). In addition to this widely adopted test, [Genomic Health](#) provides the [Oncotype DX colon cancer test](#), the first multi-gene expression test developed for the assessment of risk of recurrence in patients with [stage II and stage III](#) disease, and the Oncotype DX [prostate cancer test](#), which predicts disease aggressiveness in men with low risk disease. As of September 30, 2013, more than 19,000 physicians in over 70 countries had ordered nearly 400,000 Oncotype DX tests. The company is based in [Redwood City](#), California with European headquarters in Geneva, Switzerland. For more information, please visit, [www.GenomicHealth.com](#) and follow the company on Twitter: [@GenomicHealth](#). To learn more about OncotypeDX tests, visit: [www.OncotypeDX.com](#), [www.mybreastcancertreatment.org](#) and [www.myprostatecancertreatment.org](#).

About Almac Group

'Partnering to Advance Human Health'

The Almac Group is an established contract development and manufacturing organization that provides an extensive range of integrated services to over 600 companies globally within the pharmaceutical and biotech sectors. The services range from

[R&D, biomarker discovery and development, API manufacture, formulation development, clinical trial supply, IXRS® technology \(IVRS/IWRS\)](#) through to [commercial-scale manufacture](#).

The international company is a privately owned organization that has organically grown over 30 years and now employs in excess of 3,300 highly skilled personnel. Almac is headquartered in Craigavon, Northern Ireland with US operations based in Pennsylvania, North Carolina and California.

Almac Diagnostics is a division of Almac Group Ltd focusing on the discovery, development and delivery of novel prognostic and predictive tests.

Almac Diagnostics has a pipeline of oncology based tests in development in therapeutic areas including breast, colon, ovarian, prostate and lung cancer.

In addition Almac Diagnostics partners with the biopharmaceutical industry supporting the discovery, development and delivery of companion diagnostics.

Visit www.almacgroup.com, e-mail info@almacgroup.com

Torreya Partners LLC advised Almac Group Ltd in this transaction

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to our plans to develop and validate a test for prediction of benefit from DNA damage-based regimens including Anthracycline for High Risk Breast Cancer; the expectation that the initial study results of the Almac group will be confirmed in further studies; our plans to commercially launch an Oncotype DX test for DNA damage-based regimens including Anthracycline Benefit Assay for High Risk Breast Cancer; the potential indications for use of a test; the ability of any such test to individualize cancer treatment decisions ; the potential of the test to change medical practice for high risk breast cancer patients ; the ability of the company to develop additional tests in the future; the scope, success or results of clinical trials and the timing of such activities; the ability to meet clinical and commercial endpoints; the timing and amount of any future milestone or royalty payments; the applicability of clinical study results to actual outcomes; the ability of the company to obtain and maintain adequate reimbursement for the test; our beliefs regarding the attributes of our product pipeline; and our ability to develop 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, the results of clinical studies; the applicability of clinical study results to actual outcomes; the risks and potential delays associated with such studies; the risks, costs and potential delays associated with the commercialization of current and future products; unanticipated costs or delays in research and development efforts; risks and uncertainties associated with the regulation of and reimbursement for our tests, both domestically and abroad; our ability to compete against third parties; and the other risks set forth in the company's filings with the Securities and Exchange Commission, including the risks set forth in the company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2013. 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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