



## Clinical Data, Inc. Establishes Research Collaboration to Confirm Role of FCGR3A Pathway for Predicting Clinical Outcomes in Breast Cancer Treatment

### - Prospective Study Designed to Validate Genetic Associations and Trastuzumab Response -

NEWTON, Mass., Dec 11, 2008 (BUSINESS WIRE) --

PGxHealth, a division of Clinical Data, Inc. (NASDAQ: CLDA), today announced that it has established a research collaboration with Antonino Musolino, M.D., and the Azienda Ospedaliero - Universitaria di Parma (University Hospital of Parma), Italy, to validate the use of genetic variants in the FCGR pathways in predicting response to trastuzumab (Herceptin) therapy in patients with breast cancer. The research will include an international prospective trial to evaluate the association of genetic variants, such as the *FCGR3A* F158V genotype, with response to trastuzumab in breast cancer treatment. The collaboration expands PGxHealth's FCGR (Fc gamma receptor) program that includes its PGxPredict<sup>(R)</sup>:RITUXIMAB test for a gene variant used to determine response to rituximab monotherapy in follicular non-Hodgkin's lymphoma.

"In our pilot study, Fc gamma receptor genetic variants were strong predictors of trastuzumab efficacy in HER-2 positive metastatic breast cancer patients," said Antonino Musolino, M.D., Medical Oncology Unit, University Hospital of Parma. "Combining our efforts with PGxHealth's to confirm this result is an important step forward in optimizing breast cancer treatment and may lead to a fully validated pharmacogenetic test for targeted therapy in solid tumors."

PGxHealth scientists will collaborate with Dr. Musolino and his colleagues to analyze certain genetic variants in patients enrolled in an international trial of approximately 300 breast cancer patients receiving trastuzumab along with other drugs in the neoadjuvant setting (before primary treatment), to determine whether the *FCGR3A* F158V and other variants are predictive of clinical outcome. This study is expected to be completed by the end of 2009.

"Clinical evidence demonstrating the importance of FCGR variants in predicting the efficacy of monoclonal antibody-based cancer therapies continues to grow, and augments our own efforts related to IgG1 antibody response," said Carol R. Reed, M.D., Chief Medical Officer of Clinical Data. "By establishing collaborations with world-renowned oncology researchers, such as Dr. Musolino, we are aiding the development of genetic tests that can predict drug response and help guide treatment decisions for clinicians and their patients with cancer."

The importance of genetic variation in the FCGR3A pathway is gaining attention among researchers and clinicians, and will also be highlighted in a poster session at the 31<sup>st</sup> Annual San Antonio Breast Cancer Symposium on December 14, 2008, Poster Session VI: Prognosis and Response Predictions: Response Predictions - Biomarkers and Other Factors. The impact of the FCGR3A pathway for optimizing treatment of lymphomas, breast, and colorectal cancers with rituximab, trastuzumab and cetuximab and other recombinant mAbs was the focus of the MAb IMPACT meeting of oncology experts, held in November 2008 in Tours, France.

*FCGR3A*, a gene that encodes an Fc gamma receptor, binds both natural and therapeutic IgG1 antibodies. The FCGR3A receptor transmits signals from the membrane into the cell via tyrosine kinase activity. This signaling pathway is important in regulating antibody-dependent cellular cytotoxicity (ADCC), a mechanism that is important to the efficacy of many monoclonal antibody-based (mAbs) therapies. Recent studies have suggested that genotyping *FCGR3A* and other Fc gamma receptors may be important in predicting response to cetuximab in colorectal cancer and to trastuzumab in breast cancer<sup>1,2</sup>.

### About PGxPredict<sup>(R)</sup>:RITUXIMAB Test

PGxHealth's PGxPredict:RITUXIMAB test detects a single nucleotide polymorphism in *FCGR3A* that has been found to independently predict the response of patients with follicular non-Hodgkin's lymphoma to treatment with rituximab monotherapy. For more information, please contact 877-2-PGxHealth (877-274-9432) or visit [www.pgxhealth.com](http://www.pgxhealth.com).

### About PGxHealth

PGxHealth has extensive experience and capabilities in the development, clinical validation and delivery of genomics-based tests. Through its own know-how and resources, work conducted with some of the world's most prestigious genomics thought leaders and institutions, and use of innovative technologies, PGxHealth is focused on reducing treatment costs and improving

clinical outcomes in disease states and therapeutic classes with expensive, inefficient or suboptimal treatment options. Among its products are the *FAMILION*<sup>(R)</sup> and the *PGxPredict*<sup>(R)</sup> tests. Visit the company's website at [www.pgxhealth.com](http://www.pgxhealth.com).

## **About Clinical Data, Inc.**

Clinical Data is a global biotechnology company unlocking the potential of molecular discovery, From Targeted Science to Better Healthcare<sup>(R)</sup>. The Company's PGxHealth division is utilizing its biomarker intellectual property to develop and commercialize a broad pipeline of targeted therapeutics as well as pharmacogenetic tests that help predict drug safety and efficacy, thereby reducing health care costs. Its Cogenics division provides genomics services to both research and regulated environments. Through these divisions, Clinical Data is leveraging advances in molecular discovery to provide tangible benefits for patients, doctors, scientists and health plans worldwide. Please visit the Company's website at [www.clda.com](http://www.clda.com) for more information.

## **SAFE HARBOR STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995**

*This press release contains certain forward-looking information and statements that are intended to be covered by the safe harbor for forward looking statements provided by the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts. Words such as "expect(s)", "feel(s)", "believe(s)", "will", "may", "anticipate (s)" and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements about our ability to successfully integrate the operations, business, technology and intellectual property obtained in our acquisitions; our ability to obtain regulatory approval for, and successfully introduce our new products; our ability to expand our long-term business opportunities; financial projections and estimates and their underlying assumptions; and statements regarding future performance. All of such information and statements are subject to certain risks and uncertainties, the effects of which are difficult to predict and generally beyond the control of the Company, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include, but are not limited to, whether our PGxPredict<sup>(R)</sup> tests, including but not limited to FAMILION<sup>(R)</sup>, will gain wide acceptance in the market; the extent to which genetic markers (haplotypes) are predictive of clinical outcomes and drug efficacy and safety; the strength of our intellectual property rights; competition from pharmaceutical, biotechnology and diagnostics companies; the development of and our ability to take advantage of the market for pharmacogenetic and biomarker products and services; whether Clinical Data will be able to develop or acquire additional products and attract new business and strategic partners; and those risks identified and discussed by Clinical Data in its filings with the U.S. Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward looking statements that speak only as of the date hereof. Clinical Data does not undertake any obligation to republish revised forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. Readers are also urged to carefully review and consider the various disclosures in Clinical Data's SEC periodic and interim reports, including but not limited to its Annual Report on Form 10-K for the fiscal year ended March 31, 2008, Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2008, and Current Reports on Form 8-K filed from time to time by the Company.*

<sup>1</sup> Zhang W et al. *Journal of Clinical Oncology*. 2007 Aug 20;25(24):3712-8.

<sup>2</sup> Musolino A et al. *Journal of Clinical Oncology*. 2008 Apr 10;26(11):1789-96.

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SOURCE: Clinical Data, Inc.

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