

## NEWS

## FOR IMMEDIATE RELEASE

## **Clinical Data, Inc. Establishes Broad Research Collaboration with the University of Pittsburgh to Examine Role of FCGR3A Pathway for Predicting Clinical Outcomes in Cancer Treatment**

– Multi-disciplinary Program Builds on Evidence of Genetic Associations and Response to IgG1 Monoclonal Antibody-based Therapies –

NEWTON, Mass. – May 4, 2009 – PGxHealth, a division of Clinical Data, Inc. (NASDAQ: CLDA), today announced that it has begun a broad research collaboration with the University of Pittsburgh to discover and further validate the application of genetic variants in FCGR (Fc gamma receptor) genes, including FCGR3A, for predicting response to monoclonal antibodies (mAbs) in cancer treatment. The strategic collaboration aims to conduct a series of clinical programs to evaluate the response to mAb-based therapies, such as Erbitux (cetuximab), Rituxan (rituximab) and Herceptin (trastuzumab) and potentially other mAbs of the IgG1 subclass in treating a variety of cancers. The collaboration builds upon the large and growing body of evidence demonstrating the contribution of genetic variants in the FCGR family to mAb response in cancer treatment. It also expands PGxHealth's own FCGR program, which includes collaborations with other prominent researchers at leading institutions, and its own PGxPredict<sup>®</sup>:RITUXIMAB test for a gene variant used to determine response to rituximab monotherapy in follicular non-Hodgkin's lymphoma. Fc gamma receptors are antibody receptors found on immune-regulatory white blood cells, such as T-cells.

The initial research program is between PGxHealth and the University of Pittsburgh. Dr. Robert Ferris, Associate Professor and Chief, Division of Head and Neck Surgery at the University of Pittsburgh Cancer Institute ("UPCI"), will lead studies focusing on Erbitux in the treatment of head and neck cancer. Erbitux has been approved by the U.S. Food and Drug Administration (FDA) for use in the treatment of patients with head and neck cancer and has been shown to increase survival in this population. PGxHealth and UPCI plan to expand the scope of their research in the near term to include other cancers and treatments. The research may also extend to other disease areas where mAb therapies are important, such as rheumatoid arthritis.

"UPCI is one of the leading research institutions in the country and this collaboration represents a significant step forward in our goal to expand our Fc gamma program in oncology," said Marcia Lewis, Vice President, Biomarker Development at PGxHealth. "We intend to expand the scope of our research with UPCI to include response to other mAb-based therapies, such as Rituxan (rituximab) and Herceptin (trastuzumab) and mAbs of the IgG1 subclass, in treating a variety of cancers and other diseases where mAb therapies are used, such as rheumatoid arthritis."

The importance of genetic variation in the FCGR3A pathway continues to gain attention among researchers and clinicians. The impact of the FCGR3A pathway for optimizing treatment of

lymphomas, breast and colorectal cancers with rituximab, trastuzumab, 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 mAb 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>®</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, a division of Clinical Data, Inc., is utilizing its biomarker expertise and intellectual property to develop and commercialize targeted therapeutics as well as pharmacogenetic tests that detect serious diseases and help to predict drug safety and efficacy. By using innovative technologies and working with some of the world's most prestigious genomics thought leaders and institutions, PGxHealth is focused on improving clinical outcomes and reducing treatment costs in disease states and therapeutic classes with expensive, inefficient or suboptimal treatment options. Among its tests are the *FAMILION*<sup>®</sup> and the PGxPredict<sup>®</sup> brands. Please visit the website at [www.pgxhealth.com](http://www.pgxhealth.com)

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

Clinical Data is a global biotechnology company unlocking the potential of genomic discovery, *From Targeted Science to Better Healthcare*<sup>®</sup>. The Company is utilizing its biomarker expertise and intellectual property to develop and commercialize targeted therapeutics, as well as pharmacogenetic tests to detect serious diseases and help predict drug safety, tolerability, and efficacy, thereby improving health while reducing costs. Clinical Data is leveraging advances in molecular discovery to provide tangible benefits for patients, healthcare professionals and payors worldwide. To learn more, please visit the Company's website at [www.clda.com](http://www.clda.com).

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## **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>®</sup> tests, including but not limited to FAMILION<sup>®</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 December 31, 2008, and Current Reports on Form 8-K filed from time to time by the Company.*

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<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.