



Clinical Data, Inc. Announces Data Confirming the Value of FCGR3A Gene Variant in Predicting Rituximab Response in Non-Hodgkin's Lymphoma to be Presented at ASCO

- Results Expand on Previous Findings Showing Genotype Correlates with Response to Rituximab Induction and Maintenance Therapy -

NEWTON, Mass., Jun 03, 2010 (BUSINESS WIRE) -- [Clinical Data, Inc.](#) (NASDAQ: CLDA), today announced that data from a study of the Fc gamma 3A receptor (FCGR3A) in patients with follicular non-Hodgkin's lymphoma (NHL) validates the use of genotyping for genetic variants in the Fc gamma receptors for predicting response to rituximab. These findings, to be presented by Clinical Data's PGxHealth division at the Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, Illinois, June 4-8, 2010, build upon previous data which demonstrated that the *FCGR3A* genotype is associated with response to induction and maintenance therapy with rituximab in certain NHL patients.

"These results provide further evidence of the importance of *FCGR3A* in determining which patients are likely to benefit most from rituximab, and potentially other monoclonal antibody therapies used to treat cancer," said Marcia Lewis, Ph.D., Vice President, Biomarker Development at PGxHealth. "We continue to work with collaborators in an effort to replicate and extend the knowledge of the role of FCGR receptors in modulating response to monoclonal antibody therapies."

Abstract # 8065

Poster session: Lymphoma and Plasma Cell Disorders, **Saturday, June 5, 8 AM - Noon CT**

Predictive Value of *FCGR3A* Genotype on Response to Rituximab Induction and Maintenance Therapy in Follicular Non-Hodgkin's Lymphoma

Presenter: M. Lewis, Clinical Data, Inc.'s PGxHealth division

In a trial conducted by the Swiss Group for Clinical Cancer Research (SAKK), 306 patients with NHL were treated with rituximab induction therapy. Patients with stable disease, or partial or complete response at 12 weeks were randomized to observation or maintenance therapy with rituximab. *FCGR3A* genotype in follicular lymphoma patients was analyzed for response at 12 and 52 weeks and association of genotype with clinical endpoints was determined. Results demonstrated that F158V variant of the *FCGR3A* genotype was associated with clinical response:

- Patients with the 158V/V and 158F/V genotypes responded better to rituximab induction and maintenance therapy than those with the 158F/F genotype, suggesting that F/F patients may not benefit from rituximab maintenance therapy.
- Overall, patients with the 158V/V genotype achieved the highest response rate to prolonged treatment with rituximab monotherapy and showed the greatest benefit from maintenance (improved event-free and progression-free survival).

"The confirmatory and novel findings of this study, which address the impact of inherited, rather than tumor-derived, markers of response to monoclonal antibody therapeutics, will continue to inform development of diagnostic tests that drive individualized cancer therapies," added Dr. Lewis.

FCGR3A, a gene that encodes an Fc gamma receptor, binds both natural and therapeutic IgG1 antibodies. Upon antibody binding, the *FCGR3A* receptor transmits signals from the membrane into the cell. This signaling pathway is important in regulating antibody-dependent cellular cytotoxicity (ADCC), a mechanism that is important to the efficacy of many monoclonal antibody 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^{1,2}

About PGxPredict^(R):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.

About PGxHealth

PGxHealth, a division of Clinical Data, Inc., 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*^(R) and the PGxPredict^(R) brands. Please visit the website at www.pgxhealth.com.

About Clinical Data, Inc.

Clinical Data develops first-in-class and best-in-category therapeutics. The Company is advancing its late-stage drug candidates for [central nervous system disorders](#) and [cardiovascular diseases](#), to be followed by promising drug candidates in other major therapeutic areas. Clinical Data combines its drug development and biomarker expertise in an effort to develop products with enhanced efficacy and tolerability to improve patient health and reduce costs. To learn more, please visit the Company's website at www.clda.com.

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 obtain regulatory approval for, and successfully introduce any of our diagnostic or therapeutic products; our ability to expand our long-term business opportunities; financial projections and estimates and their underlying assumptions; and all other statements regarding future performance. All 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, risks related to whether our PGxPredict tests will gain wide acceptance in the market; the extent to which genetic markers 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; 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, 2009, Quarterly Report on Form 10-Q for the fiscal quarter ended December 31, 2009, and Current Reports on Form 8-K filed from time to time by the Company.

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

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

SOURCE: Clinical Data, Inc.

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