



Clinical Data, Inc. Reaffirms Support for Current Regulation of Laboratory-Developed Tests

- Company Opposes Genentech's Citizen Petition Advocating New FDA Regulation of All LDTs, Which Would Inhibit Innovation in Personalized Medicine -

NEWTON, Mass., Dec 16, 2008 (BUSINESS WIRE) --

Clinical Data, Inc. (NASDAQ: CLDA) announced today that it intends to oppose a Citizen Petition filed with the U.S. Food and Drug Administration (FDA) by Genentech, Inc. (NASDAQ: DNA), which requested that the agency regulate more stringently all laboratory-developed tests (LDTs) that are used to guide therapeutic decisions - tests that are the essence of personalized therapies. Clinical Data's genetic biomarker-based tests, including its PGxPredict^(R) tests to assist in predicting a patient's response to specific drugs, have been developed according to current regulatory requirements and are performed in strict compliance with the Clinical Laboratory Improvement Amendments (CLIA). The development and use of these tests are based on sound scientific evidence, and provide demonstrable clinical value in aiding physicians and patients in making more informed treatment decisions.

Clinical Data supports clear and consistent regulatory policy. The Company also endorses a degree of regulation that is necessary and sufficient. In contrast, the position advocated by Genentech ignores the fact that excessive or inappropriate regulation is a powerful disincentive to the development of innovative healthcare products that improve outcomes while lowering healthcare costs.

"Regulatory policy must continue to balance judiciously the need for new and innovative products with regulation that ensures the safety and efficacy of those products," said Henry I. Miller, M.D., a fellow at Stanford University's Hoover Institution and former senior official at the FDA. "This is, after all, the goal of the FDA's Critical Path Initiative: to facilitate the development of better tools, such as biomarkers, that diagnose disease and predict the efficacy of possible treatments. The FDA has said it is committed to bringing new products to clinicians and patients as quickly as possible: unnecessary regulatory oversight is not the solution and only hinders the scientific and medical innovation that drives the development and delivery of new therapies."

Diagnostic tests of varying degrees of sophistication and a wide spectrum of parameters have long been employed to make diagnoses and to ascertain the nature and the correct dose of a therapeutic drug. Many modalities and techniques used by physicians to make diagnoses and to guide therapeutic decisions fall outside the purview of FDA regulation. Moreover, even for products that potentially lie within the FDA's jurisdiction, the agency has "discretion" not to exercise that jurisdiction.

"LDTs provide tremendous value to clinicians and their patients, and we remain committed to expanding the clinical utility of our genetic tests through collaborations with leading academic institutions and industry partners to further the understanding of biomarkers of disease and drug response," said Carol R. Reed, M.D., Chief Medical Officer of Clinical Data. "In particular, we would welcome Genentech's assistance and collaboration in contributing samples from their many clinical programs to the growing body of evidence which has demonstrated that Fc gamma receptor (FCGR) genetic variants are predictive of efficacy of IgG1 monoclonal antibody-based cancer therapies, such as rituximab and trastuzumab."

Pharmacogenomic tests predict an individual's response to specific drugs, and the technologic advances they represent are already having a profound impact on the health of Americans--bringing about more precise diagnoses and better-suited therapies, more cost-effective utilization of our healthcare dollars, and a more efficient healthcare system. The techniques and technologies require ongoing development and enhancements, much the same way that certain drug therapies do. In order for advances to continue, regulatory policy must create appropriate incentives for their development.

Clinical Data's PGxHealth division develops and markets its *FAMILION*^(R) and PGxPredict^(R) tests. *FAMILION* tests are used to detect inherited cardiac syndromes, such as Long QT Syndrome. PGxPredict tests are designed to assist physicians in predicting response to certain drugs in individuals and includes the Company's PGxPredict^(R):RITUXIMAB test for a gene variant used to determine response to rituximab monotherapy in follicular non-Hodgkin's lymphoma.

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, a signaling pathway that is important in regulating antibody-dependent cellular cytotoxicity (ADCC), a mechanism that is important to the efficacy of many monoclonal antibody-based (mAb) therapies. If the appropriate receptor, such as the target for a therapeutic drug, is not present, the drug

will not be effective. 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 in two independent studies, to predict the response of patients with follicular non-Hodgkin's lymphoma to treatment with rituximab monotherapy. Use and interpretation of the results of the PGxPredict:RITUXIMAB test are governed by instructions and ancillary materials, including informed consent forms, provided by PGxHealth. For more information, please contact 877-2-PGxHealth (877-274-9432) or visit www.pgxhealth.com.

About FAMILION^(R) Tests

The *FAMILION* family of tests detect genetic mutations that can cause cardiac channelopathies or cardiomyopathies such as Long QT Syndrome (LQTS), Brugada Syndrome (BrS), Catecholaminergic Polymorphic Ventricular Tachycardia (CPVT), Hypertrophic Cardiomyopathy (HCM), and Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC) in individuals and their families. For more information about the *FAMILION* family of genetic tests, please contact 877-2-PGxHealth (877-274-9432) or visit www.pgxhealth.com/genetictests/familion.

About PGxHealth

PGxHealth has extensive experience and capabilities in the development and clinical validation of targeted therapeutics, and the delivery of genomics-based tests. Through its own expertise 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 PGxHealth's products are the *FAMILION*^(R) tests for use in diagnosing inherited cardiac syndromes and the PGxPredict^(R) tests for use in predicting drug response. For more information, please visit the website at 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^(R). The Company's PGxHealth division is utilizing its biomarker intellectual property to develop and commercialize a broad pipeline of targeted therapeutics as well as pharmacogenomic tests that help predict drug safety and efficacy, thereby reducing health care costs. Its Cogencis 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 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^(R) tests, including but not limited to FAMILION^(R), 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.

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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