



## Clinical Data, Inc. Reports Advances in Two Late-Stage Therapeutic Programs

### - Vilazodone(TM) and Stedivaze(TM) Phase III Trials on Track to Meet Key 2009 Milestones -

NEWTON, Mass., Jan 07, 2009 (BUSINESS WIRE) --

Clinical Data, Inc. (NASDAQ: CLDA), today announced key milestones in its two late-stage therapeutic development programs, vilazodone and Stedivaze (apadenoson). The Company reported that it has completed enrollment in the second Phase III registration trial of vilazodone for the treatment of major depression. Additionally, Clinical Data recently conducted an end of Phase II meeting with the U.S. Food and Drug Administration (FDA) for its cardiac stress imaging agent, Stedivaze, now poised to enter Phase III studies for cardiac perfusion testing. As a result, the Company is well positioned to achieve its anticipated 2009 milestones for both the vilazodone and Stedivaze Phase III clinical programs.

"We continue to make significant progress in both of our late-stage drug development programs and believe this reflects the knowledge, expertise and dedication of our clinical teams, as well as our ability to achieve and even exceed drug development goals," said Drew Fromkin, President and CEO of Clinical Data. "We look forward to reporting the results of our second Phase III registration trial of vilazodone in the spring of 2009 and initiating our Phase III program for Stedivaze in the first half of calendar 2009, as planned."

#### **Vilazodone(TM)**

Clinical Data completed patient enrollment, nearly two months ahead of schedule, in its second Phase III registration trial for vilazodone, the first in a potential new class of antidepressants. Results of the 470-patient study are still expected in the first half of calendar 2009. In addition, the Company's long-term safety study of vilazodone has approximately 300 patients continuing in the study who have been on drug for over six months. Together, these meaningful advances in the clinical trials for vilazodone enhance the probability of the Company's achieving its stated goal of filing an investigational new drug application (NDA) with the FDA for vilazodone in the treatment of major depression by calendar year-end 2009.

In the first Phase III registration study of 410 patients, vilazodone achieved statistical significance ( $p = .001$ ) in reducing the symptoms of major depression, and the drug was generally well tolerated. Importantly, the first trial also identified genetic markers of response to vilazodone. Clinical Data is seeking to confirm these markers in its second Phase III registration trial for use in developing a potential companion diagnostic. Results of the first Phase III trial of vilazodone have been accepted for publication in a major psychiatric journal, and publication is anticipated in the second half of calendar 2009.

Antidepressants represent the largest segment of the Central Nervous System drug market, accounting for greater than \$12 billion in annual sales.<sup>1</sup> Current therapies are often limited by adverse events, such as sexual dysfunction and weight gain, and patients frequently take weeks to respond to initial treatment. Poor compliance with existing therapies also remains a challenge. Vilazodone has a unique, dual mechanism of action, as both a Selective Serotonin Reuptake Inhibitor (SSRI) and a 5HT<sub>1A</sub> partial agonist, and may offer patients an important new treatment option. Drugs with these mechanisms of action are used in the treatment of depression, anxiety and other psychiatric conditions. In addition, the development of a companion diagnostic test could be used to identify those patients most likely to respond to vilazodone, enabling healthcare providers to prescribe a first-line treatment with a higher likelihood that the patient may respond, resulting in better compliance.

#### **Stedivaze(TM)**

Clinical Data met with the FDA, as planned, to review the results from Phase II studies of Stedivaze and to discuss the protocol for Phase III trials. Based on the meeting, Clinical Data believes that it has reached agreement with the FDA on the initial design elements for its Phase III studies.

"Our recent meeting with the FDA was very productive in providing us with important information to use in finalizing the design of our Phase III program for Stedivaze," said Carol R. Reed, M.D., Chief Medical Officer of Clinical Data. "We will continue to work with the Agency, and we remain committed to launch our Phase III program in the first half of calendar 2009."

Results of Phase II studies of Stedivaze in cardiac perfusion imaging demonstrated comparable diagnostic accuracy and an improved adverse event profile, when compared to an existing agent, Adenoscan (adenosine). In addition, results showed that Stedivaze had a rapid onset and offset of action, which may offer an important advantage related to the potential for improved

tolerability (i.e., reduced incidence, severity or duration of adverse events commonly reported for cardiac stress agents). Cardiac stress agents are used to dilate the coronary vasculature in the absence of exercise in order to perform myocardial perfusion testing. The U.S. market for stress imaging agents is projected to be \$800 million in 2011.<sup>2</sup> An aging population and a patient population increasingly unable to perform exercise during diagnostic procedures are projected to create greater demand for cardiac imaging agents in the future.

#### **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<sup>(R)</sup> division is utilizing its proprietary portfolio of biomarkers to develop and commercialize a broad range of targeted therapeutics as well as pharmacogenetic tests that help predict drug safety and efficacy, thereby reducing health care costs. Its Cogenics<sup>(R)</sup> 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. To learn more, please visit the Company's website at [www.clda.com](http://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 successfully continue the development of vilazodone, Stedivaze and all of our other therapeutic candidates; integrate the operations, business, technology and intellectual property obtained in our acquisitions; 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 biomarkers 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 we will be able to develop or acquire additional products and attract new business and strategic partners; and those risks identified and discussed by us in our 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. We do 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 our periodic and interim reports filed with the SEC, including but not limited to our 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>IMS Health's National Sales Perspective 2007

<sup>2</sup>AMR Monthly Monitor

SOURCE: Clinical Data, Inc.

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

Theresa McNeely, 617-527-9933 x 3373

Vice President

Corporate Communications

or

General Business Inquiries, 617-527-9933 x 3388

Copyright Business Wire 2009

News Provided by COMTEX