

NEWS

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Clinical Data, Inc. Announces Publication of Results from First Phase III Study of Vilazodone in Treatment of Major Depressive Disorder

- Findings Demonstrate Potential Effectiveness and Lack of Sexual Side Effects -

NEWTON, Mass., – March 11, 2009 – Clinical Data, Inc. (NASDAQ: CLDA) today announced the publication of the complete results from its first pivotal Phase III study of vilazodone as a potential treatment for major depressive disorder in the *Journal of Clinical Psychiatry (JCP)*. Vilazodone, if approved, could represent a new class of drugs for the treatment of depression, due to its novel dual mechanism of action as both a selective serotonin reuptake inhibitor (SSRI) and a 5HT1A partial agonist. The *JCP* publication details the findings from a randomized, double-blind, placebo-controlled study in patients with major depressive disorder. Importantly, the publication describes an adverse event profile for vilazodone with effects on sexual function comparable to placebo; many antidepressants, including SSRIs, have been associated with increased sexual dysfunction, a common symptom of depression. The *JCP* paper appears online as an Ahead of Print Article from the March 2009 issue.¹

A separate editorial, published in the March issue of the journal *Personalized Medicine*, reports additional research completed as part of the Phase III study, describing genetic biomarkers predictive of individual response to vilazodone.² Together, these publications demonstrate the potential of vilazodone in the treatment of depression and illustrate proprietary genetic biomarkers of response that may be used to identify patients likely to receive enhanced benefit from treatment with vilazodone. Currently, prescribing depression medications is a trial and error approach, taking weeks to months for patients to find the right treatment. A pharmacogenetic test, such as the one being developed alongside vilazodone, could greatly improve this process by predicting which patients are likely to have an enhanced response to vilazodone.

“There is a need for new treatments for patients suffering from depression that are both efficacious and have the potential to offer a side effect profile that does not have the negative impact on sexual function that is associated with many current therapies,” said Karl Rickels, M.D. Chief, Mood & Anxiety Disorders Program, Steward and Emily Mudd Professor of Psychiatry, Department of Psychiatry, University of Pennsylvania, lead author on the *JCP* and *Personalized Medicine* papers and a principal investigator for the vilazodone Phase III studies. “As many as 30 to 40% of patients currently on depression treatment with an SSRI report sexual side effects, which often leads to discontinuation of therapy. What we saw in this Phase III trial of vilazodone was very encouraging. Compared to placebo, there was no effect on sexual function; in fact, we observed a slight

improvement in sexual function for patients treated with vilazodone, although it did not reach statistical significance.”

“The publication of positive results from our first Phase III study in this prominent, peer-reviewed journal highlights the potential of vilazodone as a first-in-class antidepressant that is well tolerated and with positive differentiation on side effects,” said Carol R. Reed, M.D., Chief Medical Officer of Clinical Data, “Our second Phase III trial of vilazodone is nearly complete; we anticipate reporting results from this second study by the end of June, as well as submitting a New Drug Application (NDA) for vilazodone by the end of this year.”

Both publications report findings from the Phase III study, in which the primary and supportive secondary efficacy endpoints were met. The randomized, double-blind, placebo-controlled, ten-site trial enrolled 410 adult patients with major depressive disorder. In this study, patients taking vilazodone achieved a significantly ($p=0.001$) greater improvement in mean Montgomery-Asberg Depression Rating Scale (MADRS) scores over an eight week period compared to those taking placebo. Statistically significant improvement in MADRS was observed starting at week one and on each subsequent visit, suggesting a rapid onset of action. In addition, a statistically significant improvement in symptoms of anxiety was observed.

The JCP publication also described adverse events associated with vilazodone. In general, vilazodone was well tolerated. During the eight weeks of treatment, the overall discontinuation rate was approximately 25% in both the vilazodone and the placebo arms of the study. In addition, vilazodone had no significant effect on sexual function with sexual dysfunction rates comparable to that of placebo, as measured using the Arizona Sexual Experience Scale (ASEX), a five-item scale commonly used to evaluate sexual dysfunction in clinical trials. Changes in ASEX scores suggested a slight improvement in sexual function over the course of the study, although it did not reach statistical significance. The most common adverse events in patients treated with vilazodone were diarrhea, nausea and somnolence, with diarrhea occurring most frequently during dose titration, with a median duration of five days in the vilazodone group and four days in the placebo group. Only four patients treated with vilazodone discontinued due to diarrhea.

As part of the Phase III study, genetic biomarkers of response to vilazodone were identified and further details regarding these biomarkers were reported in the *Personalized Medicine* publication. An example of a proprietary biomarker correlated with efficacy is described, which shows that individuals with the genetic marker, representing about 30% of patients, experienced twice the response to vilazodone. Other genetic biomarkers were predictive of specific adverse events including gastrointestinal side effects.

About Vilazodone

Vilazodone is a dual serotonergic Phase III antidepressant that Clinical Data is developing in parallel with genetic biomarkers to guide the use of this novel antidepressant. It is both a Selective Serotonin Reuptake Inhibitor (SSRI) and a 5HT1A partial agonist. As approximately one-half of depressed patients do not achieve satisfactory results with current first-line treatment options, Clinical Data also seeks to develop a potential companion diagnostic for vilazodone which may assist physicians in matching patients with a treatment that is more likely to be effective.

About Depression and the Antidepressant Market

According to the National Institute of Mental Health (NIMH), 18.1 million Americans suffered from depression in 2007. In addition, major depressive disorder is the leading cause of disability in the US for individuals ages 15 – 44. IMS Health's National Sales Perspective reported that antidepressants generated sales of more than \$12 billion in 2008. The Surgeon General's Office also estimates that 5.3% of American adults, approximately 17 million people, suffer from depressive illness. It is believed that some people may be genetically predisposed to depression and that it may be possible to identify certain genetic biomarkers that might help to predict the likelihood of a patient's pharmacological response to a given antidepressant.

About Clinical Data, Inc.

Clinical Data is a global biotechnology company unlocking the potential of genomic discovery, *From Targeted Science to Better Healthcare*[®]. The Company's PGxHealth[®] division is utilizing its biomarker expertise and intellectual property to develop and commercialize targeted therapeutics, as well as pharmacogenetic tests that detect serious diseases to help predict drug safety and efficacy, thereby improving health and reducing 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. To learn more, please visit the Company's website at www.clda.com.

For More Information

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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[®] tests, including but not limited to FAMILION, 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; 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.

¹K Rickels, M Athanasiou, D Robinson, M Gibertini, H Whalen, & C Reed: Evidence for Efficacy and Tolerability of Vilazodone in the Treatment of Major Depressive Disorder: A Randomized, Double-Blind, Placebo-Controlled Trial. *The Journal of Clinical Psychiatry*. Published Electronically Ahead of Print. <http://www.psychiatrist.com>.

²K Rickels, M Athanasiou & C Reed: Vilazodone, a novel dual-acting antidepressant: current status, future promise and potential for individualized treatment of depression. *Personalized Medicine* 6(2), 217–224 (2009) DOI: 10.2217/17410541.6.2.217...<http://www.futuremedicine.com/loi/pme>

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