



Clinical Data, Inc. Announces Approval of Generic Name Vilazodone, First in a New Class of Experimental Treatments for Depression

NEWTON, Mass., Jun 19, 2009 (BUSINESS WIRE) -- [Clinical Data, Inc.](#) (NASDAQ: CLDA) announced today that the United States Adopted Name Council (USAN) has approved the generic name vilazodone hydrochloride. [Vilazodone](#), if approved, would represent a first-in-class drug for the treatment of depression, due to its novel dual mechanism of action as both a potent and selective serotonin reuptake inhibitor (SSRI) and a partial agonist of the 5-hydroxytryptamine 1a (5-HT_{1A}) receptor. Thus, vilazodone combines first-line therapy for depression with 5-HT_{1A} partial agonism, an accepted adjunctive treatment for depression and a first-line therapy for anxiety disorders. Clinical Data has recently completed the second of two positive Phase III registration studies. Results of these studies will form the basis of a new drug application (NDA) that the Company intends to submit with the U.S. Food and Drug Administration (FDA) by the end of 2009.

The purpose of the USAN Council is to select simple, informative and unique nonproprietary names for drugs based on pharmacological and/or chemical relationship. The American Medical Association, the United States Pharmacopeial Convention and the American Pharmacists Association sponsor the Council. The Council works closely with the World Health Organization's International nonproprietary Name Program.

On June 2, 2009, Clinical Data announced top-line results from its second Phase III studies for vilazodone, with results confirming its prior positive Phase III trial. Vilazodone was generally well-tolerated and met both the primary and secondary endpoints of the study with high statistical significance. In addition, study findings corroborate that effects of vilazodone on sexual function were comparable to placebo when measured by an objective validated scale, an important finding since many antidepressants have been associated with causing or exacerbating sexual dysfunction. In this second study, the most frequent side effects associated with vilazodone were diarrhea, nausea, and headache.

The Company has projected that its current cash will be sufficient to fund operations through the submission of the NDA for vilazodone this year, as well as the commencement of its Phase III clinical program for Stedivaze, a vasodilator used for cardiac stress testing, anticipated in the next month. Management continues to evaluate additional sources of financing including partnering opportunities with pharmaceutical or biotechnology companies for development and marketing of late-stage or pre-clinical compounds, sale of non-core assets and the sale of equity or debt securities.

At March 31, 2009, the Company reported cash and marketable securities totaling \$56.4 million. Based on its cash position, Clinical Data received a going concern explanatory paragraph in the unqualified audit opinion included in its Annual Report on Form 10-K which was filed with the Securities and Exchange Commission on Monday, June 15, 2009. This announcement is required by NASDAQ Marketplace Rule 4350(b)(1)(B), which requires separate disclosure of receipt of an audit opinion containing a going concern qualification. This announcement does not represent any change to the Company's Annual Report on Form 10-K or the financial statements included therein.

About Depression and the Anti-Depressant 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 individuals ages 15-44. IMS Health's National Prescription Audit reported more than 200 million prescriptions for antidepressants in 2008. The Surgeon General's Office also estimates that 5.3% of American adults, approximately 17 million people, suffer from depressive illness.

About Clinical Data, Inc.

Clinical Data is a biotechnology company focused on the discovery, development and commercialization of targeted therapeutics: From Targeted Science to Better Healthcare^(R). Clinical Data is leveraging advances in molecular discovery to provide tangible benefits for patients, healthcare professionals and payors worldwide. The Company is advancing its late-stage, first-in-class or potential best-in-category drug candidates including vilazodone, for the treatment of depression, and Stedivaze, a vasodilator used for cardiac stress testing, to be followed by promising drug candidates in other therapeutic areas such as inflammatory diseases and oncology. Coupled with its biomarker expertise and portfolio of intellectual property, Clinical Data plans to develop and commercialize targeted therapeutics, as well as genetic and pharmacogenomic tests to detect serious diseases and help predict drug safety, tolerability, and efficacy, thereby improving patient health while reducing 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 vilazodone; our ability to expand our long-term business opportunities; 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, whether vilazodone will advance further in the clinical trials process and whether and when, if at all, vilazodone will receive final approval from the U.S. Food and Drug Administration and equivalent foreign regulatory agencies and for which indications; whether vilazodone will be successfully marketed if approved; 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; general economic downturns; 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, 2008, and Current Reports on Form 8-K filed from time to time by the Company.

SOURCE: Clinical Data, Inc.

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