



Clinical Data, Inc. Initiates Phase III Trial of Stedivaze for Cardiac Stress Testing

NEWTON, Mass., Nov 18, 2009 (BUSINESS WIRE) -- [Clinical Data, Inc.](#) (NASDAQ: CLDA) today announced that it has enrolled the first patient in its initial Phase III trial of Stedivaze(TM), a potential best-in-class vasodilator for use in cardiac stress testing. The study will evaluate the safety and efficacy of Stedivaze (apadenoson) for use as a pharmacologic stress agent in myocardial perfusion imaging (MPI), a method for detecting defects in the blood supply to the heart. The Phase III trial will also compare the tolerability of Stedivaze to adenosine, a standard pharmacologic stress agent used in MPI scans.

"The superior selectivity and pharmacokinetic profile of Stedivaze support its potential for improved tolerability compared to adenosine, as seen in Phase II studies," said Carol R. Reed, M.D., Executive Vice President and Chief Medical Officer of Clinical Data. "Our Phase III trial is designed to demonstrate that these attributes, combined with a convenient, fixed, single-dose bolus administration, may offer the best-in-class pharmacologic agent for use in cardiac stress testing."

The Phase III ASPECT Trial (Apadenoson Single Photo Emission Computed Tomography) is a randomized, double blind, active control study designed to determine whether Stedivaze is as effective as adenosine when used as a pharmacologic stress agent in SPECT MPI studies. Approximately 750 patients will be enrolled over an 18 to 24 month period at investigative sites in the U.S. Patients in the study will first undergo a clinically indicated SPECT MPI and then be randomized to receive a second SPECT MPI using either adenosine or Stedivaze. The incidence and severity of commonly reported side effects, such as shortness of breath, chest pain, dizziness, and headache, will also be evaluated to determine whether Stedivaze exhibits improved tolerability compared to adenosine.

About Stedivaze

Stedivaze (apadenoson) is a potent agonist of the adenosine A_{2A} receptor subtype and offers improved selectivity over other adenosine receptor subtypes (A_1 and A_{2B}). Phase II studies suggest that Stedivaze produces ample coronary vasodilatory activity needed for cardiac stress MPI and has a pharmacokinetic profile that will allow it to be administered as a fixed dose bolus injection. Because of its improved selectivity for the A_{2A} receptor subtype and its optimal pharmacokinetic profile, Stedivaze may offer improved tolerability over other adenosine receptor agonists currently marketed for use in pharmacologic stress MPI. Stedivaze is in Phase III clinical development for use as a pharmacologic agent for myocardial perfusion imaging with the goals of demonstrating equal efficacy and improved tolerability compared to adenosine.

About Myocardial Perfusion Imaging

Myocardial perfusion imaging is used as a primary screen to identify the presence of coronary artery disease (CAD) as evidenced by detection of areas of poor blood flow in the heart that can be caused by the formation of plaques that block the normal flow of blood to the heart. A pharmacologic stress agent is used to increase blood flow through coronary arteries temporarily during stress testing in order to more strikingly define areas of the heart that receive poor blood flow. The A_{2A} adenosine receptor is the receptor subtype responsible for coronary vasodilation, or the widening of blood vessels.¹

The U.S market for MPI testing is projected to be \$800 million. Over 7.6 million MPI tests were performed in the United States in 2008 and approximately 3.5 million of these tests required the use of a pharmacological agent to generate maximum coronary blood flow in lieu of exercise.² The market is expected to continue to grow due to an increasing aging population, a rise in the number of patients unable to perform exercise during diagnostic procedures, and emerging imaging modalities that require the use of a vasodilator.

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 is also combining its drug development and biomarker expertise 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.

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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 our new 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 Stedivaze or any of our therapeutic products will advance further in the clinical trials process and whether and when, if at all, they will receive final approval from the U.S. Food and Drug Administration and equivalent foreign regulatory agencies and for which indications; whether Stedivaze or any of our other therapeutic products will be successfully marketed if approved; 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 September 30, 2009, and Current Reports on Form 8-K filed from time to time by the Company.

¹Shryock, J.C., Snowdy, S., Baraldi, P.G., et al., "A_{2A} - adenosine Receptor Reserve for Coronary Vasodilation," *Circulation*, 1998, pp. 711-718.

²AMR Monthly Monitor SNM: Advanced Molecular Imaging and Therapy, September 15, 2008.

SOURCE: Clinical Data, Inc.

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