



Amicus Therapeutics Suspends Enrollment for Phase 2 Clinical Trial of AT2220 for Pompe Disease

CRANBURY, N.J., Feb 27, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Amicus Therapeutics (Nasdaq: FOLD) announced today that the Company has suspended enrollment for the Phase 2 clinical trial of its investigational drug AT2220 (1-deoxynojirimycin HCl) for the treatment of Pompe Disease and that it has received verbal notice from the U.S. Food and Drug Administration (FDA) that the trial is on clinical hold. After evaluation of available data the Company plans to work closely with the FDA and if appropriate will amend the Phase 2 protocol with the objective of restarting the trial as expeditiously as possible.

Amicus initiated the Phase 2 clinical trial of AT2220 in adults with Pompe disease in June, 2008. Based on encouraging safety data from both preclinical and Phase 1 studies, the approved Phase 2 trial protocol involved initial treatment with a high dose of AT2220. Two patients enrolled in the trial experienced self-reported adverse events and subsequently withdrew from the trial. The events were categorized by the site investigator as serious and probably related to treatment with AT2220.

After initial evaluation of the events, Amicus suspended patient enrollment for the Phase 2 trial. In compliance with regulatory requirements and internal standard operating procedures, the two events were reported to the relevant health authorities, including FDA, and in a subsequent discussion with the FDA the trial was placed on clinical hold status pending further evaluation of the events.

John F. Crowley, President and CEO of Amicus commented, "We will work closely with the investigators and the FDA to address these issues, modify the protocol as appropriate, and get the trial back on track as quickly as possible. We are committed to exploring this new therapy for people living with Pompe disease in as safe a manner as possible."

The Company previously announced that the Phase 2 results with AT2220 will be available in the second half of 2009. The Company will provide updated guidance for reporting results in the upcoming months.

These events have no impact on Amicus' ongoing studies with its investigational drugs Amigal(TM) (migalastat hydrochloride) for Fabry disease and Plicera(TM) (afegostat tartrate) for Gaucher disease.

About the Phase 2 Trial with AT2220

Amicus initiated a multi-national, open-label Phase 2 clinical trial designed to enroll 18 adult patients diagnosed with Pompe disease. The primary objective of the study is to evaluate the safety and tolerability of different dosing regimens of AT2220 over a 12-week period. The study will also explore certain pharmacodynamic and pharmacokinetic measures including the effect of treatment with AT2220 on GAA activity and on glycogen levels in various cells and tissues. Additional objectives include preliminary assessments of pulmonary and skeletal muscle function. Participants who complete the study may be eligible to participate in a voluntary extension study that will further evaluate the effect of AT2220 on these functional parameters.

Additional information about the Phase 2 study is posted at www.clinicaltrials.gov.

The initiation of the Phase 2 study of AT2220 followed completion of multiple Phase 1 studies of AT2220 in healthy volunteers. Data from the Phase 1 studies in 72 healthy volunteers demonstrated that AT2220 was generally safe and well tolerated at all doses evaluated with no drug-related serious adverse events.

Amicus is developing AT2220 as part of a strategic collaboration with Shire Human Genetic Therapies (HGT), a business unit of Shire plc, to develop and commercialize Amicus' three lead pharmacological chaperone compounds for lysosomal storage disorders. Under the agreement, Shire received commercial rights outside of the United States. Amicus retains all U.S. rights.

About Pompe Disease

Pompe disease affects an estimated 5,000-10,000 individuals world-wide and is clinically heterogeneous in the age of onset, the extent of organ involvement, and the rate of progression. The early onset form of the disease is the most severe, progresses most rapidly, and is characterized by musculoskeletal, pulmonary, gastrointestinal, and cardiac symptoms that

usually lead to death from cardio-respiratory failure between 1 and 2 years of age. The late onset form of the disease begins between childhood and adulthood and has a slower rate of progression that is characterized by musculoskeletal and pulmonary symptoms that usually lead to progressive muscle weakness and respiratory insufficiency. A high majority of patients have the late onset form of the disease. The U.S. Food and Drug Administration's Office of Orphan Products Development has granted orphan drug designation for the active ingredient in AT2220 in the United States.

About Amicus Therapeutics

Amicus Therapeutics is a biopharmaceutical company developing novel, oral therapeutics known as pharmacological chaperones for the treatment of a range of human genetic diseases. Pharmacological chaperone technology involves the use of small molecules that selectively bind to and stabilize proteins in cells, leading to improved protein folding and trafficking, and increased activity. Amicus is initially targeting lysosomal storage disorders, which are severe, chronic genetic diseases with unmet medical needs. Amicus has completed Phase 2 clinical trials of Amigal for the treatment of Fabry disease and is conducting Phase 2 clinical trials of Plicera for the treatment of Gaucher disease and AT2220 for the treatment of Pompe disease.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as, but not limited to, "look forward to," "believe," "expect," "anticipate," "estimate," "intend," "plan," "targets," "likely," "will," "would," "should" and "could," and similar expressions or words identify forward-looking statements. Such forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. The inclusion of forward-looking statements should not be regarded as a representation by Amicus that any of its plans will be achieved. Any or all of the forward-looking statements in this press release may turn out to be wrong. They can be affected by inaccurate assumptions Amicus might make or by known or unknown risks and uncertainties. For example, with respect to statements regarding the goals, progress, timing and outcomes of ongoing discussions with and submissions to regulatory authorities and the potential goals, progress, timing and results of clinical trials, actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in the business of Amicus, including, without limitation: the potential inability to address questions raised by regulatory agencies and to receive approval for phase 2 trial design, the potential that results of clinical or pre-clinical studies indicate that the product candidates are unsafe or ineffective; the potential that the phase 2 trial for AT2220 is not resumed in a timely manner, or at all, and, our dependence on third parties in the conduct of our clinical studies. Further, the results of earlier clinical trials may not be predictive of future results. Additionally, all forward looking statements are subject to other risks detailed in our Annual Report on Form 10-K for the year ended December 31, 2008, and our other public filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, and Amicus undertakes no obligation to revise or update this news release to reflect events or circumstances after the date hereof. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

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