Amicus Therapeutics Announces Preliminary Results of Phase 2 Study with Plicera(TM) for Gaucher Disease

CRANBURY, N.J., Oct 02, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Amicus Therapeutics (Nasdaq: FOLD) today announced preliminary results from its Phase 2 randomized, open-label study to assess the safety, tolerability and preliminary efficacy of its investigational drug, Plicera(TM) (afegostat tartrate), in treatment-naive adult patients with type 1 Gaucher disease. Two dose regimens of Plicera (225 mg three days on/four days off and seven days on/seven days off) were studied during this six month trial. While all patients enrolled experienced an increase in the level of the target enzyme (GCase) as measured in white blood cells, clinically meaningful improvements in key measures of disease were observed in just one of the eighteen patients who completed the study. The preliminary results suggest that treatment with Plicera was generally well tolerated, with no serious adverse events (SAEs) reported. Nineteen subjects were enrolled and 18 subjects completed the study. One subject discontinued treatment because of an adverse event (conjunctivitis-related symptoms).

Once the data are final, the Company plans to further analyze and evaluate the results in collaboration with its partner, Shire Human Genetic Therapies, Inc. (Shire HGT), and, based on this work, will determine the appropriate next steps for the Plicera program. However, based on these preliminary results, the Company does not expect to advance Plicera into Phase 3 development at this time.

John F. Crowley, President and CEO of Amicus, stated, "The preliminary results of this Phase 2 study certainly do not meet our expectations, but we believe they do provide additional insights into the biological activity of Plicera in Gaucher disease and the pharmacological chaperone technology platform. We plan a detailed analysis to ensure we have a complete understanding of the data."

The Company is also today announcing a change to its financial guidance for 2009. Based on its current projections of net operating expense, the Company now expects to end 2009 with approximately $70-$80 million in cash.

Conference Call and Webcast

Amicus will host a conference call to discuss the Plicera Phase 2 preliminary results, today, October 2, 2009, at 5 p.m. EDT. Interested participants and investors may access the conference call by dialing 888-263-2958. A telephonic replay of the call will be available for seven days beginning at 8 p.m. EDT. Access numbers for this replay are 888-203-1112; participant code 4377067.

An audio webcast can also be accessed via the investor section of the Amicus Therapeutics Web site at *www.amicustherapeutics.com* under Investors: Events and Presentations. Web participants are encouraged to go to the Web site 15 minutes prior to the start of the call to register, download and install any necessary software. After the live webcast, an audio webcast replay will remain available in the Investors section of the Amicus Therapeutics Web site for 30 days.

Amicus' press releases are available at *www.amicustherapeutics.com*.

About Gaucher Disease

Gaucher disease is a lysosomal storage disorder caused by inherited genetic mutations in the GBA gene, which result in deficient activity of the enzyme acid beta-glucosidase, also known as glucocerebrosidase (GCase). Deficient GCase activity leads to lysosomal accumulation of glucocerebroside inside certain cells, which is believed to cause the various symptoms of Gaucher disease, including an enlarged liver and spleen, abnormally low levels of red blood cells and platelets, and skeletal complications. In some cases there is significant impairment of the central nervous system.

Gaucher disease is estimated to affect approximately 10,000 people in the developed world. The U.S. Food and Drug Administration's Office of Orphan Products Development has granted orphan drug designation for the active ingredient in Plicera in the United States and the European Commission has designated Plicera as an orphan medicinal product in the European Union.

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 a strategic collaboration with Shire Human Genetic Therapies, Inc., a wholly-owned subsidiary 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.

Forward-Looking Statements

This press release contains and the accompanying conference call will contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating to clinical development of Amicus' investigational drug product, Plicera(TM) (afegostat tartrate) the timing and reporting of final results from clinical trials evaluating Amicus' investigational drug products, and the projected cash position for the Company at the end of 2009. 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 potential goals, progress, timing and final 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 that results of clinical studies indicate that the product candidates are unsafe or ineffective; the potential that clinical studies could be delayed because we identify serious side effects or other safety issues; and, our dependence on third parties in the conduct of our clinical studies. Further, the results of earlier preclinical studies and/or clinical trials may not be predictive of future results. Additionally, with respect to statements regarding projections of the Company's cash position and expected use of cash during 2009, actual results may differ based on market factors, the Company's ability to execute its operational and budget plans, and its achievement of milestones and receipt of milestone payments and reimbursements from Shire. 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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