



Amicus Therapeutics Presents Positive Results From Phase 2 Extension Study of Amigal (TM) for Fabry Disease at ACMG 2009 Annual Meeting

--Data provide support for expected Phase 3 program

CRANBURY, N.J., March 28, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Amicus Therapeutics (Nasdaq: FOLD) announced today positive results from its ongoing Phase 2 extension study of its investigational drug, Amigal(TM) (migalastat HCL) for Fabry disease. The results will be presented at the American College of Medical Genetics (ACMG) 2009 Annual Meeting in Tampa, FL.

Phase 2 Extension Study Overview:

Twenty-six subjects completed either 12 or 24 weeks of treatment during Phase 2 studies. Twenty-three of the 26 subjects continue to receive treatment in an ongoing extension study designed to evaluate the long term safety and efficacy of Amigal. Ten of the 23 subjects have been on treatment for at least 2 years and 4 subjects have been on treatment for more than 3 years.

Preliminary Results:

Treatment with Amigal was generally well-tolerated, with no drug-related serious adverse events. The most common adverse events were headache, arthralgia and diarrhea.

Subjects identified as responders to Amigal at the completion of the Phase 2 studies continued to maintain elevated levels of the target enzyme (a-Gal A), as measured in white blood cells, and reduced levels of the target substrate (kidney GL-3), as measured in urine.

A reduction of GL-3 levels was also observed in interstitial capillary cells from kidney biopsies. Previously reported Phase 2 results indicated that little to no GL-3 was detected in these cells in most subjects prior to treatment with Amigal. The new data were obtained from the retesting of biopsies using an improved methodology.

Preliminary results from the evaluation of modified doses and a new dosing regimen were also presented.

Derralynn Hughes, MA, DPhil, MRCPATH, Senior Lecturer in the Haematology Department Academic Haematology, Royal Free & University College Medical School, London, UK, stated, "The data with migalastat continue to be encouraging. I believe migalastat has the potential to be an important new treatment option for Fabry patients."

John F. Crowley, President and CEO of Amicus Therapeutics, added, "We are very pleased with this additional set of Phase 2 data and are very confident we have a solid basis for a successful Phase 3 program. We continue to work in collaboration with the FDA and remain on track to finalize our protocol and initiate the Phase 3 program in the second quarter of this year."

In January 2009, Amicus announced that the FDA supports a Phase 3 clinical trial comparing Amigal to placebo based on a surrogate primary endpoint of the change in the amount of kidney GL-3, the substrate that accumulates in the cells of Fabry patients. The Company expects to finalize the protocol and initiate Phase 3 development in the second quarter of this year.

Amicus is developing Amigal 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 Fabry Disease

Fabry disease is a lysosomal storage disorder caused by inherited genetic mutations in the GLA gene, which result in deficient activity of the enzyme alpha-galactosidase A (a-Gal A). Deficient a-Gal A activity leads to lysosomal accumulation of globotriaosylceramide (GL-3), which is believed to cause the various symptoms of Fabry disease, including pain, kidney failure and increased risk of heart attack and stroke. Amigal is designed to selectively bind to and stabilize a-Gal A, which facilitates proper trafficking of the enzyme to the lysosomes, where it is needed to break down GL-3.

Fabry disease is estimated to affect approximately 5,000 to 10,000 people in the developed world, but recent evidence suggests that the disease may be significantly under-diagnosed. The U.S. Food and Drug Administration's Office of Orphan Products Development has granted orphan designation for Amigal in the United States, and the European Commission has designated Amigal as an orphan medicinal product in the European Union.

About Shire plc

Shire's strategic goal is to become the leading specialty biopharmaceutical company that focuses on meeting the needs of the specialist physician. Shire focuses its business on attention deficit and hyperactivity disorder (ADHD), human genetic therapies (HGT) and gastrointestinal (GI) diseases as well as opportunities in other therapeutic areas to the extent they arise through acquisitions. Shire's in-licensing, merger and acquisition efforts are focused on products in specialist markets with strong intellectual property protection and global rights. Shire believes that a carefully selected and balanced portfolio of products with strategically aligned and relatively small-scale sales forces will deliver strong results.

For further information on Shire, please visit the Company's website: www.shire.com.

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.

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 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 reach final agreement with regulatory agencies on the use of a surrogate endpoint and phase 3 trial design for Amigal, the potential that the interim results of the phase 2 extension study may not be predictive of the final results of the study, the potential that results of clinical or pre-clinical studies indicate that the product candidates are unsafe or ineffective; 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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