



Amicus Therapeutics Announces Positive Progress of Three Lead Clinical Programs and General Outlook for 2009

CRANBURY, N.J., Jan 12, 2009 /PRNewswire-FirstCall via COMTEX News Network/ --

Company Expects to Deliver Multiple Clinical Milestones throughout the Year; Amigal to Initiate Phase 3 Global Development in Second Quarter; Continued Strong Financial Position

Amicus Therapeutics (Nasdaq: FOLD) today announced positive progress in its three lead clinical programs for lysosomal storage disorders and presented a corporate outlook consisting of multiple clinical milestones and financial guidance for 2009 at the 27th Annual J.P. Morgan Healthcare Conference. The Company also provided an update on its interactions with U.S. and European regulatory agencies that are expected to lead to the commencement of Phase 3 clinical development for Amigal(TM) (migalastat hydrochloride), an oral therapeutic drug candidate for the treatment of Fabry disease. Amicus, along with its partner, Shire Human Genetic Therapies, Inc. (Shire HGT), plans to initiate Phase 3 development of Amigal for the treatment of Fabry disease in the second quarter of 2009. Amicus also reviewed data on the potential for the combination of pharmacological chaperones and enzyme replacement therapy (ERT).

"We continue to make significant advancements in our clinical programs and we expect this to progress through several key milestones which we plan to deliver in 2009. Combined with our financial strength, our partnership with Shire HGT, and the growing breadth of our pharmacological chaperone technology platform, we feel this progress sets the stage for a transformational year for our company," said John F. Crowley, Amicus' President and CEO.

CLINICAL PROGRAM ADVANCEMENTS

Amigal (migalastat hydrochloride) for the treatment of Fabry Disease

Amicus previously announced in August 2008 that it had completed a successful End of Phase 2 meeting with the U.S. Food and Drug Administration (FDA). At that time, the FDA indicated that the data from the completed Phase 2 clinical studies of Amigal support the initiation of Phase 3 development and that Amigal was eligible for Accelerated Approval under Subpart H regulations. The FDA further indicated at that time that it was not opposed to the use of a surrogate primary endpoint, pending further discussions with the company.

Following this End of Phase 2 meeting, Amicus continued discussions with the FDA in the second half of 2008. The Agency has indicated that it 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. Amicus plans to continue discussions with the FDA through a Special Protocol Assessment (SPA) procedure that it commenced in the fourth quarter of 2008 to finalize how the primary endpoint will be measured. Amicus expects the SPA process to be complete in the second quarter of this year.

Based on discussions with the European Medicines Agency (EMA), Amicus expects to initiate a separate clinical study designed to evaluate the safety and efficacy of Amigal versus ERT in Fabry patients. Amicus and its partner Shire HGT plan additional discussions with the EMA in the first half of 2009 to finalize the design of this study.

In parallel with the Phase 3 regulatory discussions, 23 of the original 26 patients from the Phase 2 studies continue to be treated in a voluntary extension study to characterize the long-term safety and efficacy of Amigal and to evaluate additional doses and dose regimens. Data from this extension study are expected to be available in the first quarter of 2009 and the results will be used to finalize the dose and regimen for the Phase 3 studies.

Plicera(TM) (isofagomine tartrate) for the treatment of Gaucher Disease

A Phase 2 clinical trial of Plicera in Gaucher patients is ongoing. This 6 month study is designed to evaluate safety as well as to demonstrate trends of efficacy as measured by the standard endpoints in Gaucher disease. Target enrollment of 16 patients for this study is expected to be surpassed and the results are expected to be available in the third quarter of 2009.

In addition, Amicus is working closely with its partner Shire HGT to prepare for Phase 3 development of Plicera pending the

results of the ongoing Phase 2 trial.

AT2220 (1-deoxynojirimycin HCl) for the treatment of Pompe Disease

A Phase 2 clinical trial of AT2220 in adult Pompe patients is ongoing. The trial includes an 11 week treatment period with an optional extension study. The objectives of the trial include the evaluation of the safety and pharmacodynamics of multiple doses and regimens of AT2220. The results of this study are expected to be available in the second half of 2009.

In addition, Amicus is continuing to conduct preclinical animal studies to evaluate the effects of administering AT2220 in combination with ERT. Encouraging preliminary results were announced at the American Society of Human Genetics conference in November 2008. These results indicated that AT2220 in combination with ERT significantly increases the stability and tissue uptake of ERT. Amicus is conducting additional preclinical proof-of-concept studies to determine the feasibility of a combination that may be appropriate for Pompe patients who are not amenable to chaperone monotherapy. Amicus expects to announce additional results in the first quarter of 2009.

2009 FINANCIAL GUIDANCE

Amicus expects to spend a total of approximately \$70 million on 2009 cash operating expenses, to be offset by \$50 million in program cost-sharing reimbursements and clinical milestone payments from Shire. Amicus anticipates ending 2009 with approximately \$100 million in cash.

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.

Amicus has a strategic collaboration with Shire Human Genetic Therapies, Inc., a wholly-owned subsidiary of Shire Limited, 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 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.

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 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, 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 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, 2007, 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.

FOLD-G

SOURCE Amicus Therapeutics

<http://www.amicustherapeutics.com/>

Copyright (C) 2009 PR Newswire. All rights reserved

News Provided by COMTEX