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Amicus Therapeutics Achieves Target Enrollment in Second Phase 3 Fabry Monotherapy Study

56 Patients Now Randomized to Switch from Enzyme Replacement Therapy (ERT) to Migalastat HCl or to Remain on ERT

Final Enrollment Expected Ahead of Year-End Target

CRANBURY, N.J., Oct. 22, 2012 (GLOBE NEWSWIRE) -- Amicus Therapeutics (Nasdaq:FOLD), a biopharmaceutical company at the forefront of developing therapies for rare and orphan diseases, today announced that it has now achieved target enrollment and has 56 patients in its second Phase 3 study (Study 012) of migalastat HCl monotherapy for Fabry disease. Screening is now closed at participating sites, and final enrollment is anticipated by year-end 2012. Amicus, in collaboration with GlaxoSmithKline (GSK), is developing the investigational pharmacological chaperone Migalastat HCl for the treatment of Fabry disease.

Study 012 (The ATTRACT, or FAB-AT1001-012 Study) Highlights:

- First clinical study to compare oral migalastat HCl to standard-of-care ERTs (Fabrazyme® and Replagal®)
- Enrolled males and females with Fabry disease, who had genetic mutations amenable to migalastat HCl as a monotherapy, and were on ERT for a minimum of 12 months
- Primary outcome measure is renal function assessed by Glomerular Filtration Rate (GFR) at 18 months

John F. Crowley, Chairman and Chief Executive Officer of Amicus, stated, "We are very pleased to have met the enrollment objectives for this important Phase 3 Fabry monotherapy study ahead of the year-end target. The willingness of these Fabry patients to switch from an approved ERT to migalastat HCl to participate in this study highlights the unmet medical needs that persist in this community. We look forward to evaluating the effects of migalastat HCl, as well as currently used ERTs, on renal function over the course of 18 months of treatment in this study."

Amicus and GSK are co-developing all formulations of migalastat HCl under a global Fabry collaboration. Migalastat HCl monotherapy is in Phase 3 development (Study 011 and Study 012) for Fabry patients with genetic mutations that are amenable to this chaperone monotherapy, as determined by a cell-based assay. Study 011 is a placebo-controlled study intended primarily to support U.S. registration, and Study 012 compares migalastat HCl to ERT to primarily support global registration. Migalastat HCl co-administered with ERT is in Phase 2 (Study 013) and migalastat HCl co-formulated with JCR Pharmaceutical Co. Ltd's proprietary ERT (JR-051, recombinant human alpha-Gal A enzyme) is in preclinical development. Amicus has commercial rights to all Fabry products in the United States and GSK has commercial rights to all of these products in the rest of world.

About Amicus Therapeutics

Amicus Therapeutics (Nasdaq:FOLD) is a biopharmaceutical company at the forefront of developing therapies for rare and orphan diseases. The Company is developing orally administered, small molecule drugs called pharmacological chaperones, a novel, first-in-class approach to treating a broad range of human genetic diseases. Amicus' late-stage programs for lysosomal storage disorders include migalastat HCl monotherapy in Phase 3 for Fabry disease; migalastat HCl co-administered with enzyme replacement therapy (ERT) in Phase 2 for Fabry disease; and AT2220 (duvoglustat HCl) co-administered with ERT in Phase 2 for Pompe disease.

About Study 012

Study 012 (The ATTRACT, or FAB-AT1001-012 Study) is a randomized, open-label 18-month Phase 3 study investigating the safety and efficacy of oral migalastat HCl (150 mg, every-other-day) compared to standard-of-care infused therapy using ERTs (Fabrazyme® and Replagal®). The study recruited males and females with Fabry disease and genetic mutations shown to be amenable to migalastat HCl monotherapy in a cell-based assay. All subjects had been receiving ERT infusions for a minimum of 12 months (at least 3 months at the labeled dose). The primary outcome measure is renal function assessed by Glomerular Filtration Rate (GFR) at 18 months, evaluated in the migalastat HCl and ERT groups using descriptive statistics. More

information about this study can be found at www.clinicaltrials.gov: NCT01218659.

About Fabry Disease

Fabry disease is an inherited lysosomal storage disease that is currently estimated to affect approximately 5,000 to 10,000 people worldwide. It is caused by deficiency of an enzyme called alpha-galactosidase A (alpha-Gal A). The role of alpha-Gal A within the body is to break down a complex lipid called globotriaosylceramide (GL-3). Reduced or absent levels of alpha-Gal A activity leads to the accumulation of GL-3 in the affected tissues, including the kidney, heart, central nervous system, and skin. This accumulation of GL-3 is believed to cause the various signs and symptoms of Fabry disease, including pain, kidney failure, and increased risk of heart disorders and stroke.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating to clinical development of Amicus' candidate drug products and the timing and reporting of results from clinical trials evaluating Amicus' candidate drug products. 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 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 or pre-clinical studies indicate that the product candidates are unsafe or ineffective; the potential that it may be difficult to enroll patients in our clinical trials; the potential that regulatory authorities may not grant or may delay approval for our product candidates; the potential that preclinical and clinical studies could be delayed because we identify serious side effects or other safety issues; the potential that we will need additional funding to complete all of our studies 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. In addition, all forward looking statements are subject to other risks detailed in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2012. 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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