May 31, 2016

Amicus Therapeutics Announces European Commission Approval for Galafold™ (Migalastat) in Patients with Fabry Disease in European Union

Launch has Begun in Germany

Broad Label for All Fabry Patients with an Amenable Genetic Mutation

First Precision Medicine Approved for Fabry Disease

CRANBURY, N.J., May 31, 2016 (GLOBE NEWSWIRE) -- Amicus Therapeutics (Nasdaq:FOLD), a biotechnology company at the forefront of rare and orphan diseases, today announced that the European Commission has granted full approval for the oral small molecule pharmacological chaperone Galafold™ (migalastat) as a first line therapy for long-term treatment of adults and adolescents aged 16 years and older with a confirmed diagnosis of Fabry disease (alpha-galactosidase A deficiency) and who have an amenable mutation. Amicus began supplying the market in Germany on Monday, May 30, 2016 and will commence the reimbursement processes with healthcare authorities in each of the major European countries.

Galafold is the first oral treatment as well as the first precision medicine for Fabry disease. The broad label includes 269 Fabry-causing mutations which represent 35 percent to 50 percent of all patients with Fabry disease. The label also references a website www.galafoldamenabilitytable.com where EU healthcare providers can quickly and accurately determine which mutations are amenable to Galafold.

"This EU approval for Galafold is a significant advancement in the field of precision genetic medicine and a tremendous milestone for the Fabry community," said John F. Crowley, Chairman and Chief Executive Officer of Amicus Therapeutics, Inc. "This approval also completes our transformation to a global, fully-integrated, commercial biotechnology company focused on rare and devastating diseases. Our world-class commercial and business leadership team has done an outstanding job preparing for this day. We have begun the launch of Galafold in Germany and will commence the country-by-country reimbursement processes throughout the EU. We are grateful for the ongoing support from our Amicus employees and the Fabry community, in particular those physicians and patients who participated in the clinical studies of Galafold and their families who made this approval possible. As we move forward with the commercial launch of Galafold, we will continue to invest in the innovation of our pipeline. Our vision today is more focused than ever - to build on our strong science and clinical experience to bring forward the highest quality therapies for Fabry, Pompe, EB and other rare and devastating diseases."

The EC approval was based on clinical data from two Phase 3 pivotal studies in both treatment naïve (Study 011, or FACETS) and enzyme replacement therapy (ERT) switch patients (Study 012, or ATTRACT), as well as ongoing long-term extension studies. Fabry disease is a rare genetic disease and potentially life-threatening condition caused by the accumulation of disease substrate (globotriaosylceramide, GL-3) in the lysosome due to a dysfunctional or deficient enzyme. Galafold works by stabilizing the body's own dysfunctional enzyme, so it can clear the accumulation of disease substrate in patients who have amenable mutations. An amenable mutation is one that is responsive to therapy with Galafold based on predefined criteria.

"As principal investigator in both Galafold pivotal studies, I have experience treating both naïve and treatment-experienced Fabry patients with Galafold," said Derralynn Hughes MA DPhil FRCP FRCPath, Senior Lecturer in Haematology at University College London, UK with clinical responsibilities in haematology and lysosomal storage disorders. "I am pleased that the European Commission has approved this new treatment option and I believe it has the potential to address unmet needs among Fabry patients who have amenable mutations."

"The EU approval of the first oral precision medicine for Fabry disease is a major step forward for patients in Europe," said Christine Lavery, President of the Fabry International Network (FIN). "We appreciate Amicus' commitment to the Fabry community and its dedication to develop high quality therapies for Fabry disease. For the first time in more than a decade, patients with Fabry disease who have amenable mutations now have a choice for an innovative new treatment option."

François Eyskens, MD, PhD, Department of Experimental Medicine and Pediatrics, University of Antwerp, Antwerpen, stated, "During my 20 years in treating Fabry disease, I am convinced that it is underdiagnosed and that significant unmet need

remains among these patients. Galafold is an innovative oral precision medicine with a unique mechanism of action that has demonstrated compelling results in naïve and treatment-experienced Fabry patients who have amenable mutations. I am looking forward to offering a differentiated treatment option for the many Fabry patients who have an amenable mutation."

The EC approval of Galafold follows the unanimous April 2016 positive opinion granted by the Committee for Medicinal Products for Human Use (CHMP) and applies to all 28-member states of the EU and Liechtenstein, with final authorization pending in Iceland and Norway. The EC approval provides a platform to begin accessing the more than 70 percent of the Fabry global market, including the EU member states as well as several international territories that accept the EC approval as the basis for marketing submissions. The Company is also pursuing independent regulatory processes in several international territories outside of Europe, including Japan, Australia and Canada. Amicus also expects to meet with the U.S. Food and Drug Administration (FDA) in the middle of 2016 to clarify a potential U.S. regulatory pathway for Galafold.

About Galafold™ and Amenable Mutations

Galafold is a first-in-class chaperone therapy approved in the EU as a monotherapy for Fabry disease in patients with amenable mutations. Galafold works by stabilizing the body's own dysfunctional enzyme, so it can clear the accumulation of disease substrate in patients who have amenable mutations. A proprietary *in vitro* assay (Galafold Amenability Assay) was used to classify more than 800 known GLA mutations as "amenable" or "not amenable" to treatment with Galafold. The current label includes all 269 GLA mutations that have been identified and determined to be amenable based on the Galafold Amenability Assay, which represent between 35% and 50% of the currently diagnosed Fabry population.

Healthcare providers in the EU may access the website [www.galafoldamenabilitytable.com] to quickly and accurately identify which mutations are categorized as "amenable" or "not amenable" to Galafold. Amicus expects to submit updates to the label as additional GLA mutations are identified and tested in the Galafold Amenability Assay.

Important Safety Information

Treatment with GALAFOLD should be initiated and supervised by specialists experienced in the diagnosis and treatment of Fabry disease. GALAFOLD is not recommended for use in patients with a nonamenable mutation.

- GALAFOLD is not intended for concomitant use with enzyme replacement therapy.
- GALAFOLD is not recommended for use in patients with Fabry disease who have severe renal impairment (< 30 mL/min/1.73 m^2). The safety and efficacy of GALAFOLD in children 0-15 years of age have not yet been established.
- No dosage adjustments are required in patients with hepatic impairment or in the elderly population.
- There is very limited experience with the use of this medicine in pregnant women. If you are pregnant, think you may be pregnant, or are planning to have a baby, do not take this medicine until you have checked with your doctor, pharmacist, or nurse.
- While taking GALAFOLD, you should use effective birth control should be used. It is not known whether GALAFOLD is excreted in human milk.
- Contraindications to GALAFOLD include hypersensitivity to the active substance or to any of the excipients listed in the PRESCRIBING INFORMATION.
- It is advised to periodically monitor renal function, echocardiographic parameters and biochemical markers (every 6 months) in patients initiated on GALAFOLD or switched to GALAFOLD.
- OVERDOSE: General medical care is recommended in the case of GALAFOLD overdose.
- The most common adverse reaction reported was headache, which was experienced by approximately 10% of patients who received GALAFOLD. For a complete list of adverse reactions, please review the SUMMARY OF PRODUCT CHARACTERISTICS.
- Call your doctor for medical advice about side effects.

About Fabry Disease

Fabry disease is an inherited lysosomal storage disorder caused by deficiency of an enzyme called alpha-galactosidase A (alpha-Gal A), which are the result of mutations in the GLA gene. The primary biological function of alpha-Gal A is to degrade specific lipids in lysosomes, including globotriaosylceramide (referred to here as GL-3 and also known as Gb_3). Lipids that can be degraded by the action of alpha-Gal A are called "substrates" of the enzyme. Reduced or absent levels of alpha-Gal A activity lead to the accumulation of GL-3 in the affected tissues, including the central nervous system, heart, kidneys, and skin. Progressive accumulation of GL-3 is believed to lead to the morbidity and mortality of Fabry disease, including pain, kidney failure, heart disease, and stroke. The symptoms can be severe, differ from patient to patient, and begin at an early age. All Fabry disease is progressive and leads to organ damage regardless of the time of symptom onset.

About Amicus Therapeutics

Amicus Therapeutics (Nasdaq:FOLD) is a biotechnology company at the forefront of therapies for rare and orphan diseases. The Company has a robust pipeline of advanced therapies for a broad range of human genetic diseases. Amicus' lead programs in development include the small molecule pharmacological chaperone migalastat as a monotherapy for Fabry disease, SD-101 for Epidermolysis Bullosa (EB), as well as novel enzyme replacement therapy (ERT) products for

Fabry disease, Pompe disease, and other lysosomal storage disorders.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating to preclinical and clinical development of our product candidates, the timing and reporting of results from preclinical studies and clinical trials, the prospects and timing of the potential regulatory approval of our product candidates, commercialization plans, financing plans, and the projected cash position for the Company. The inclusion of forward-looking statements should not be regarded as a representation by us that any of our plans will be achieved. Any or all of the forward-looking statements in this press release may turn out to be wrong and can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. For example, with respect to statements regarding the goals, progress, timing, and outcomes of discussions with regulatory authorities, and in particular the potential goals, progress, timing, and results of preclinical studies and clinical trials and the expected timing of the EMA's final decision with respect to regulatory approval of migalastat in the European Union, actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in our business, including, without limitation: the potential that results of clinical or preclinical 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, including the EMA, may not grant or may delay approval for our product candidates; the potential that we may not be successful in commercializing our product candidates if and when approved; the potential that preclinical and clinical studies could be delayed because we identify serious side effects or other safety issues; and the potential that we will need additional funding to complete all of our studies. Further, the results of earlier preclinical studies and/or clinical trials may not be predictive of future results. With respect to statements regarding projections of the Company's cash position, actual results may differ based on market factors and the Company's ability to execute its operational and budget plans. In addition, all forward-looking statements are subject to other risks detailed in our Annual Report on Form 10-K for the year ended December 31, 2015 and our First Quarter Report on Form 10-Q.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 we undertake no obligation to revise or update this news release to reflect events or circumstances after the date hereof.

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