Amicus Therapeutics Awarded United Kingdom Prix Galien Medal for Galafold® (Migalastat)

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First Orphan Drug to Win Prestigious “Innovative Product” Award

CRANBURY, N.J. and LONDON, Dec. 11, 2018 (GLOBE NEWSWIRE) -- Amicus Therapeutics (Nasdaq: FOLD), a global biotechnology company focused on discovering, developing and delivering novel medicines for rare metabolic diseases, today announced that Galafold® (migalastat) was awarded the 2018 UK Prix Galien Medal for Innovative Product. The Prix Galien is awarded to companies who have made significant advances in pharmaceutical research, and is regarded as the highest accolade for biomedical research and development.

John F. Crowley, Chairman and Chief Exeutive Officer of Amicus Therapeutics, Inc., stated, “We are honored to receive the prestigious UK Prix Galien medal for Galafold, the first ever orphan drug to win in the Innovative Product category. We believe that this award embodies the efforts among our team at Amicus, together with patients, physicians and the broader Fabry community, to globally develop and deliver Galafold as a medicine for certain individuals who are diagnosed with Fabry disease and who have an amenable *GLA* mutation, or variant. The Prix Galien awards are considered by many to be the industry’s equivalent of a Nobel Prize, and we are grateful to the Galien Foundation for this very important recognition.”

“The 2018 Awards yet again confirmed the depth and diversity of innovation in UK life sciences. The success of products for rare disease – which, for the first time, dominated the shortlist of finalists – shows that innovation is not confined to Big Pharma or treatments for major headline conditions," said Karen Westaway, Chief Executive of ValueBase, owners of Prix Galien’s UK franchise.

Galafold is approved in the European Union (EU), U.S., Australia, Canada, Israel, Japan, South Korea and Switzerland.

About Prix Galien
The Prix Galien Awards were founded in France in 1970 to celebrate the endeavours of scientists, researchers and industry to develop innovations that advance the treatment of human disease. The Prix Galien Awards are held in 17 countries. The UK Prix Galien Awards are held every two years at the Houses of Parliament, London. Since its inception in 1990, just 36 products have won a coveted UK Prix Galien medal, including some of the industry’s most iconic brands. The 2018 UK Prix Galien awards recognized innovation across four categories: Innovative Product, Orphan Product, Real World Evidence and Medical Device.

About Galafold®
Galafold® (migalastat) 123 mg capsules is an oral pharmacological chaperone of alpha-Galactosidase A (alpha-Gal A) for the treatment of Fabry disease in adults who have amenable *GLA* variants. In these patients, Galafold works by stabilizing the body’s own dysfunctional enzyme so that it can clear the accumulation of disease substrate. Globally, Amicus Therapeutics estimates that approximately 35 to 50 percent of Fabry patients may have amenable *GLA* variants, though amenability rates within this range vary by geography. Galafold is approved in Australia, Canada, European Union, Israel, Japan, South Korea, Switzerland and the U.S.

U.S. INDICATIONS AND USAGE
Galafold is indicated for the treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (*GLA*) variant based on *in vitro* assay data.

This indication is approved under accelerated approval based on reduction in kidney interstitial capillary cell globotriaosylceramide (KIC GL-3) substrate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

U.S. IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS
The most common adverse reactions reported with Galafold (≥10%) were headache, nasopharyngitis, urinary tract infection, nausea and pyrexia.

USE IN SPECIFIC POPULATIONS
There is insufficient clinical data on Galafold use in pregnant women to inform a drug-associated risk for major birth defects and miscarriage. Advise women of the potential risk to a fetus.

It is not known if Galafold is present in human milk. Therefore, the developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for Galafold and any potential adverse effects on the breastfed child from Galafold or from the underlying maternal condition.

Galafold is not recommended for use in patients with severe renal impairment or end-stage renal disease requiring dialysis.

The safety and effectiveness of Galafold have not been established in pediatric patients.

To report Suspected Adverse Reactions, contact Amicus Therapeutics at 1-877-4AMICUS or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For additional information about Galafold, including the full U.S. Prescribing Information, please visit https://www.amicusrx.com/pi/galafold.pdf.

About Fabry Disease
Fabry disease is a rare, progressive genetic disorder characterized by a defective gene (*GLA*) that causes an enzyme deficiency. This enzyme is responsible for breaking down disease substrate that, when deficient in patients with Fabry disease, builds up in the kidneys, which is one of the organ systems impacted by Fabry disease.

About Amicus Therapeutics
Amicus Therapeutics (Nasdaq: FOLD) is a global, patient-dedicated biotechnology company focused on discovering, developing and delivering novel high-quality medicines for people living with rare metabolic diseases. With extraordinary patient focus, Amicus Therapeutics is committed to advancing and expanding a robust pipeline of cutting-edge, first- or best-in-class medicines for rare metabolic diseases. For more information please visit the company's website at www.amicusrx.com, and follow us on Twitter and LinkedIn.

Forward-Looking Statements
This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. 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. 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, 2017 as well as our Quarterly Report on Form 10-Q for the quarter September 30, 2018 filed November 6, 2018 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 we undertake no obligation to revise or update this news release to reflect events or circumstances after the date hereof.

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