Amicus Therapeutics Announces Preliminary 2019 Galafold Revenue - Exceeding Upper End of Prior Guidance

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Galafold Revenue of $181 Million for Full-Year 2019 and $54 Million in Q4 Reflects Continued Strong Adoption & Patient Adherence in All Key Global Regions

Galafold Marketing Authorizations Recently Received in Brazil, Colombia and Taiwan

Galafold on Track for $500M Revenue by 2023 with Potential for $1B Peak Revenue

Galafold Revenue Target for 2020 to be Announced at 38th Annual J.P. Morgan Healthcare Conference

CRANBURY, N.J., Jan. 09, 2020 (GLOBE NEWSWIRE) -- Amicus Therapeutics (Nasdaq: FOLD), a global, patient dedicated biotechnology company focused on discovering, developing and delivering novel medicines for rare metabolic diseases, today announced preliminary 2019 revenue and Galafold (migalastat) commercial updates.

John F. Crowley, Chairman and Chief Executive Officer of Amicus Therapeutics stated, “2019 represented another period of significant growth and adoption for Galafold across all geographies. We are pleased to announce our commercial performance surpassed our expectations for the year. This reflects the strong continued adoption of this novel precision medicine for Fabry patients with amenable mutations as well as the 90%+ continued adherence and compliance rates seen with patients. We are also pleased to have recently received notice of three new marketing authorizations in key countries that occurred late in the fourth quarter. These achievements highlight our company’s mission, which is focused on transforming the lives of people living with rare diseases, and for Galafold to ensure broad, worldwide access as soon as possible for all Fabry patients who may benefit.”

Fourth Quarter and Full Year 2019 Revenue
Global revenue for Galafold in full-year 2019 was approximately $181 million (preliminary and unaudited) representing a year-over-year increase of 99% from total revenue of $91 million in 2018 and exceeded the Company’s updated 2019 guidance of $170 million to $180 million. Full-year revenue was negatively impacted by approximately $5 million in foreign currency headwinds. Fourth quarter Galafold revenue was approximately $54 million (preliminary and unaudited).

Marketing Authorizations
In 2019, Amicus made significant progress expanding access to Galafold around the globe, including most recently in Brazil, Colombia and Taiwan. Each of these countries granted approval for the first-in-class, oral small molecule precision medicine pharmacological chaperone Galafold (migalastat), as a monotherapy. Galafold is the first and only oral precision medicine for Fabry disease approved in these countries.

In Brazil, Amicus is working to complete the requirements to launch Galafold in the coming months. As part of the approval process for rare diseases in the country, patients will initially be required to go through a court injunction process, which will take approximately one year before receiving access to medication. Therefore, the Company expects more meaningful revenue contribution to begin in 2021 and beyond.

Galafold is approved in over 40 countries around the world, including the U.S., EU, Japan and others.

Amicus management will present a corporate overview and 2020 guidance at the 38th Annual J.P. Morgan Healthcare Conference in San Francisco, CA on Tuesday, January 14, 2020 at 8:30 a.m. PT. A Q&A breakout session will immediately follow the presentation at 9:00 a.m. PT.

Live audio webcasts of the presentation and breakout session will be available and can be accessed through the Investors section of the Amicus Therapeutics corporate website at http://ir.amicusrx.com/, and will be archived for 90 days.

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 over 40 countries around the world, including the U.S., EU, Japan and others.

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.

EU 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, 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.

For further important safety information for Galafold, including posology and method of administration, special warnings, drug interactions and adverse drug reactions, please see the European SmPC for Galafold available from the EMA website at www.ema.europa.eu.

About Fabry Disease
Fabry disease is an inherited lysosomal disorder caused by deficiency of an enzyme called alpha-galactosidase A (alpha-Gal A), which results from 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 Gb3). 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 heart, kidneys, and skin. Accumulation of GL-3 and progressive deterioration of organ function is believed to lead to the morbidity and mortality of Fabry disease. The symptoms can be severe, differ from person to person, and begin at an early age.

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.

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