



Amicus Therapeutics Confirms Business Continuity, 2020 Strategic Priorities and Announces Proactive Efforts to Support Public Health Initiatives, Patients & Employees

March 23, 2020

CRANBURY, N.J., March 23, 2020 (GLOBE NEWSWIRE) -- [Amicus Therapeutics](#) (Nasdaq: FOLD), a global, patient-dedicated biotechnology company focused on discovering, developing and delivering novel medicines for rare diseases, today announced that the Company has proactively taken numerous measures in response to the novel coronavirus (COVID-19) pandemic to support the rare disease community globally and to ensure the achievement of its 2020 key strategic priorities. In support of its patients, people, and programs, a COVID-19 internal Amicus task force chaired by Chairman & CEO John F. Crowley was established in early March and meets regularly via video conference to assess COVID-19 developments and their impacts on company plans and strategies.

Our Patients. Amicus is committed to providing uninterrupted access to medicines for those who are in need of a treatment.

- Global supply chains for Galafold[®] are robust and have not been interrupted. Amicus believes the Company will continue to be able to supply this oral precision medicine for any and all people living with Fabry disease who have an amenable variant.
- The Company also has a high degree of confidence that participants enrolled in all clinical studies for AT-GAA for Pompe disease, including the Phase 3 PROPEL study, will continue to receive study drug and that this study will be completed on schedule.
- The Company has taken steps to reinforce and elevate the resources provided to patient community partners, which is also detailed on our corporate [website](#).

Our People. Amicus is aligned with public health strategies designed to prevent the spread of COVID-19 in order to protect our global workforce.

- In addition to instituting social distancing efforts, the Company mandated a work from home policy for all global Amicus offices as of March 12, 2020.
- Amicus is focused on ensuring the health and wellbeing of its global workforce and maintaining the safety of all our employees across the globe. The *Amicus Cares* internal initiative was launched last week to respond to the needs of employees during this unprecedented global health crisis.
- Company executives and medical personnel are also advising and assisting with local, state and federal authorities in certain instances.

Our Programs. Amicus remains dedicated to delivering high-quality medicines for people living with rare diseases. Toward that end, Amicus has instituted a business continuity plan that it believes ensures the business will continue to perform and deliver on its mission for patients and shareholders. Based on current information, the Company continues to believe it will achieve its 2020 key strategic priorities, including:

- Achieve \$250 million to \$260 million of global product revenue for Galafold
- Complete Pompe Phase 3 PROPEL study, enroll pediatric studies and advance manufacturing to support 2021 BLA and MAA of AT-GAA
- Advance clinical development, manufacturing and regulatory discussions for CLN6 and CLN3 Batten programs
- Progress Pompe gene therapy towards IND and disclose up to two additional IND candidates
- Maintain strong financial position

As a leader in the global rare-disease community, our top priority remains our patients, communities and employees. We will continue to monitor the overall situation closely as it applies to all our partners and share updates appropriately.

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, U.K, 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 ($\geq 10\%$) 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>.

E.U. and U.K. 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 ($< 30 \text{ mL/min/1.73 m}^2$). 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 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 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 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, manufacturing and supply plans, financing plans and the projected revenues and 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, statements regarding corporate goals and the attainment of such goals, including as they are impacted by Covid-19 related disruption, are based on current information. The potential impact on operations from the Covid-19 outbreak is inherently unknown and cannot be predicted with confidence and may cause actual results and performance to differ materially from the statements in this release, including without limitation, because of the impact on general political and economic conditions, including as a result of efforts by governmental authorities to mitigate Covid-19, such as travel bans, shelter in place orders and third-party business closures and resource allocations, manufacturing and supply chain disruptions, limitations on patient access to commercial product or clinical trial sites and investigational product or other clinical study disruptions. With respect to statements regarding projections of the Company's financial outlook, actual results may differ based on Covid-19 related disruptions and other market factors, including the factors above, and the Company's ability to execute its business continuity, 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, 2019. 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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