

Amicus Therapeutics to Highlight Fabry Disease Program at the 13th International Congress of Inborn Errors of Metabolism (ICIEM)

CRANBURY, N.J., Aug. 25, 2017 (GLOBE NEWSWIRE) -- Amicus Therapeutics (Nasdaq:FOLD), today announced that 6 posters highlighting its Fabry program will be included in the <u>13th International Congress of Inborn Errors of Metabolism</u> to be held September 5-8, 2017 in Rio de Janeiro, Brazil.

Poster Sessions: Wednesday, September 6, 2017 from 5:30-8:00pm BRT (4:30-7:00pm EDT)

- Long-Term Migalastat Treatment Stabilizes Renal Function in Patients With Fabry Disease: Results From a Phase 3 Clinical Study (AT1001-041) Prof Charles Lourenco, MD, University of Sao Paulo, Brazil (P-638)
- Effects of Treatment With Migalastat on the Combined Endpoint of Kidney Globotriaosylcermide Accumulation and Diarrhea in Patients With Fabry Disease: Results From the Phase 3 FACETS Study Raphael Schiffmann, MD, Institute of Metabolic Disease, Baylor Research Institute, Dallas, TX (P-645)
- Efficacy and Safety of Migalastat, an Oral Pharmacological Chaperone for Fabry Disease: Renal Findings From Two Randomized Phase 3 Studies (FACETS and ATTRACT) Ana Jovanovic, MD, Salford Royal Hospital and NHS Foundation Trust, Manchester, UK (P-636)
- Response of Patients With Fabry Disease With the Amenable GLA Mutation p.N215S to Treatment With Migalastat Prof Ulla Feldt-Rasmussen, MD, PhD, Department of Medical Endocrinology, Rigshospitalet Copenhagen University Hospital, Copenhagen, Denmark (P-644)
- Improvements in Cardiac Mass and Function With Long-Term Migalastat Treatment in Patients With Fabry Disease: Results From Phase 3 Trials Ana Jovanovic, MD, Salford Royal Hospital and NHS Foundation Trust, Manchester, UK (P-2667)
- A Next-Generation Fabry Enzyme Replacement Therapy: Co-formulation of a Proprietary Recombinant Human α-Galactosidase A With a Pharmacological Chaperone Has Greater Efficacy Than Agalsidase β in Mice Su Xu, PhD, Amicus Therapeutics, Inc. Cranbury, USA (P-2576)

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 m²). 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 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) and biologic products for Fabry disease, Pompe disease, and other rare and devastating diseases.

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 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 clinical trials, 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 FDA, EMA, and PMDA, 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; 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 for any of our product candidates. In addition, all forward-looking statements are subject to other risks detailed in our previous filings with the SEC and in our Annual Report on Form 10-K for the year ended December 31, 2016 and our Quarterly Report on Form 10-Q for the guarter ended June 30, 2017. 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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