



Amicus Therapeutics Provides EU Regulatory Update for AT-GAA

November 7, 2022

PHILADELPHIA, Nov. 07, 2022 (GLOBE NEWSWIRE) -- [Amicus Therapeutics](#) (Nasdaq: FOLD), a patient-dedicated global biotechnology company focused on developing and commercializing novel medicines for rare diseases, today provided an EU regulatory update for AT-GAA. Earlier this morning, the Committee for Medicinal Products for Human Use (CHMP) issued the agenda for their November meeting indicating possible oral explanations for miglustat and for cipaglucosidase alfa on November 9th. The Company has now been informed that oral explanations will not take place as originally anticipated. The Company continues to prepare for a CHMP opinion on AT-GAA as early as December 2022 and will assess any potential change in timelines.

About AT-GAA

[AT-GAA](#) is an investigational two-component therapy that consists of cipaglucosidase alfa (ATB200), a unique recombinant human acid alpha-glucosidase (rhGAA) enzyme with optimized carbohydrate structures, particularly bis-phosphorylated mannose-6 phosphate (bis-M6P) glycans, to enhance uptake into cells, administered in conjunction with miglustat (AT2221), a stabilizer of cipaglucosidase alfa.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating timing of the potential regulatory approval of AT-GAA. 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. 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.

CONTACTS:

Investors:

Amicus Therapeutics
Andrew Faughnan
Executive Director, Investor Relations
afaughnan@amicusrx.com
(609) 662-3809

Media:

Amicus Therapeutics
Diana Moore
Head of Global Corporate Communications
dmoore@amicusrx.com
(609) 662-5079

FOLD-G