Amicus Therapeutics Announces Settlement of Galafold® (migalastat) Patent Litigation with Teva

October 17, 2024 at 7:00 AM EDT

Company Grants Teva a License to Market Generic Galafold® Beginning in January 2037

PRINCETON, N.J., Oct. 17, 2024 (GLOBE NEWSWIRE) -- Amicus Therapeutics (Nasdaq: FOLD) today announced that it has entered into a License Agreement (Agreement) with Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals, Inc. (collectively Teva). This Agreement resolves the patent litigation brought by Amicus in response to Teva's Abbreviated New Drug Application (ANDA) seeking approval to market a generic version of GALAFOLD® (migalastat) 123mg capsules prior to expiration of the applicable patents.

Pursuant to the terms of the Agreement, Amicus will grant Teva a license to market its generic version of GALAFOLD® *in the United States* beginning on January 30, 2037, if approved by the U.S. Food and Drug Administration (FDA) and unless certain limited circumstances customarily included in these types of agreements occur. In accordance with the Agreement, the parties will terminate all ongoing Hatch-Waxman litigation between Amicus and Teva regarding GALAFOLD® patents pending in the U.S. District Court for the District of Delaware. The litigation will continue against Aurobindo[1] as the remaining active party and the litigation stay remains in place for Lupin[2].

As required by law, the companies will submit the confidential license agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review.

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 diseases. With extraordinary patient focus, Amicus Therapeutics is committed to advancing and expanding a pipeline of cutting-edge, first- or best-in-class medicines for rare diseases. For more information please visit the company's website at www.amicusrx.com, and follow on X and LinkedIn.

Forward Looking Statement
This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including but not limited to, statements concerning: the terms of the settlement agreement with Teva, expectations regarding the impact of the settlement agreement and submission of the settlement agreement for review to the United States Federal Trade Commission and the United States Department of Justice. The company cautions that forward-looking statements are inherently uncertain. Although the company believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, the forward-looking statements are neither promises nor guarantees and they are necessarily subject to a high degree of uncertainty and risk. Actual performance and results may differ materially from those expressed or implied in the forward-looking statements due to various risks and uncertainties, including the unfavorable outcome of other litigation, including so-called "Paragraph IV" litigation and other patent litigation, related to GALAFOLD, which may lead to competition from generic drug manufacturers; the outcome of any review of the settlement agreement by the United States Federal Trade Commission and United States Department of Justice; the U.S. FDA may approve Teva's ANDA significantly in advance of the entry date; and those risks and uncertainties described under the heading "Risk Factors" in the company's most recent Annual Report on Form 10-K for the year ended December 31, 2023, and on Form 10-Q for the quarter ended June 30, 2024. 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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[1] Aurobindo Pharma LTD and Aurobindo Pharma USA, Inc.

[2] Lupin LTD and Lupin Pharmaceuticals, Inc.