



United Therapeutics Announces Settlement Of Patent Litigation With Actavis Laboratories FL, Inc. Relating To Orenitram

February 16, 2018

SILVER SPRING, Md. and RESEARCH TRIANGLE PARK, N.C., Feb. 15, 2018 /PRNewswire/ -- United Therapeutics Corporation (NASDAQ: UTHR) announced today that it has entered into a Settlement Agreement with Actavis Laboratories FL, Inc. ("Actavis") resolving ongoing litigation concerning certain patents relating to United Therapeutics' product, Orenitram® (treprostinil) Extended-Release Tablets, and Actavis' Abbreviated New Drug Application ("ANDA") seeking approval by the U.S. Food and Drug Administration to market a generic version of Orenitram.

Under the Settlement Agreement, United Therapeutics granted to Actavis a license to manufacture and commercialize the generic version of Orenitram described in its ANDA filing in the United States beginning on June 15, 2027, although Actavis may be permitted to enter the market earlier under certain circumstances.

The license included in the Settlement Agreement does not permit Actavis to manufacture a generic version of any other United Therapeutics product, such as Tyvaso® (treprostinil) Inhalation Solution or Remodulin® (treprostinil) Injection. The Settlement Agreement does not grant Actavis any rights other than those required to launch Actavis' generic version of Orenitram.

In accordance with the Settlement Agreement, the parties will submit the Settlement Agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review, and will also terminate the pending litigation concerning patents relating to Actavis' ANDA.

About United Therapeutics

United Therapeutics Corporation is a biotechnology company focused on the development and commercialization of innovative products to address the unmet medical needs of patients with chronic and life-threatening conditions. [uthr-g]

Forward-looking Statements

Statements included in this press release that are not historical in nature are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, among others, statements regarding the potential launch of generic competition for Orenitram. These forward-looking statements are subject to certain risks and uncertainties, such as those described in our periodic and other reports filed with the Securities and Exchange Commission that could cause actual results to differ materially from anticipated results. Such forward-looking statements are qualified by the cautionary statements, cautionary language and risk factors set forth in our periodic reports and documents filed with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. We claim the protection of the safe harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. We are providing this information as of February 15, 2018 and assume no obligation to update or revise the information contained in this press release whether as a result of new information, future events or any other reason.

ORENITRAM, REMODULIN and TYVASO are registered trademarks of United Therapeutics Corporation.

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