



February 18, 2016

United Therapeutics Receives Paragraph IV Notice Letter For Orenitram

SILVER SPRING, Md. and RESEARCH TRIANGLE PARK, N.C., Feb. 18, 2016 /PRNewswire/ -- United Therapeutics Corporation (NASDAQ: UTHR) announced receipt of a Paragraph IV Certification Notice Letter on February 18, 2016 from Actavis Laboratories FL, Inc. (Actavis) advising that Actavis has submitted an Abbreviated New Drug Application (ANDA) to the U.S. Food and Drug Administration (FDA) requesting approval to market a generic version of the 2.5 mg strength of Orenitram[®] (treprostinil) Extended-Release Tablets.

In the Notice Letter, Actavis states that it intends to market a generic version of Orenitram before the expiration of U.S. Patent No. 7,417,070, which expires in July 2026; U.S. Patent No. 7,544,713, which expires in July 2024; U.S. Patent No. 8,252,839, which expires in May 2024; U.S. Patent No. 8,349,892, which expires in January 2031; U.S. Patent No. 8,410,169, which expires in February 2030; U.S. Patent No. 8,497,393, which expires in December 2028; U.S. Patent No. 9,050,311, which expires in May 2024; and U.S. Patent No. 8,747,897, which expires in October 2029. The Notice Letter states that the ANDA contains a Paragraph IV Certification alleging that these patents are not valid, not enforceable, and/or will not be infringed by the commercial manufacture, use or sale of the proposed product described in Actavis ANDA submission.

United Therapeutics intends to vigorously enforce its intellectual property rights relating to Orenitram, including the patents mentioned above, which are listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations list (the Orange Book).

United Therapeutics currently is reviewing the Notice Letter, which was directed to eight of the nine Orange Book-listed patents for Orenitram. The only patent not included expires in October 2017. United Therapeutics has 45 days from receipt of the Notice Letter to commence a patent infringement lawsuit against Actavis to trigger a stay precluding FDA from approving Actavis's ANDA for up to 30 months or entry of judgment holding the patents invalid, unenforceable, or not infringed, whichever occurs first.

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 diseases.

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 enforcement of our intellectual property rights. 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, which could cause actual results to differ materially from anticipated results. These risks and uncertainties include, among others, our ability to successfully enforce our intellectual property rights, and 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 18, 2016, 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. [uthr-g]

ORENITRAM is a registered trademark of United Therapeutics Corporation.

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