



United Therapeutics Receives Paragraph IV Notice Letter for Remodulin

SILVER SPRING, Md., Feb. 6, 2012 /PRNewswire/ -- United Therapeutics Corporation (NASDAQ: UTHR) today announced receipt of a Paragraph IV Certification Notice Letter on February 3, 2012 from Sandoz Inc. (Sandoz) advising that Sandoz 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 10 mg/mL strength of Remodulin® (treprostinil) injection.

In the Notice Letter, Sandoz states that it intends to market a generic version of Remodulin before the expiration of U.S. Patent No. 5,153,222, which expires in October 2014; U.S. Patent No. 6,765,117, which expires in October 2017; and U.S. Patent No. 7,999,007, which expires in March 2029. Sandoz's 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 Sandoz's ANDA submission.

United Therapeutics intends to vigorously enforce its intellectual property rights relating to Remodulin, including the three patents mentioned above which are listed in the FDA's Approved Drug Products List (the Orange Book).

United Therapeutics currently is reviewing the Notice Letter, which was directed to all three Orange Book-listed patents. United Therapeutics has 45 days from receipt of the Notice Letter to commence a patent infringement lawsuit against Sandoz. Such a lawsuit would automatically preclude the FDA from approving Sandoz's ANDA for up to 30 months or until the issuance of a district court decision that is adverse to United Therapeutics, whichever occurs first.

About United Therapeutics

United Therapeutics Corporation is a biotechnology company focused on the development and commercialization of unique products to address the unmet medical needs of patients with chronic and life-threatening cardiovascular and infectious diseases and cancer.

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, that 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 6, 2012, 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]

REMODULIN is a registered trademark of United Therapeutics Corporation.

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