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United Therapeutics Announces Decision From Patent Trial And Appeal Board And Issuance Of New Patents

SILVER SPRING, Md. and RESEARCH TRIANGLE PARK, N.C., March 31, 2017 /PRNewswire/ -- United Therapeutics Corporation (NASDAQ: UTHR) today announced that the U.S. Patent and Trademark's Office (USPTO) Patent Trial and Appeal Board (PTAB) issued a Final Written Decision in connection with the *inter partes* review (IPR) of United Therapeutics' U.S. Patent No. 8,497,393 (the '393 patent). The PTAB found that all claims of the '393 patent are not patentable. United Therapeutics is evaluating its options, including the possibility of immediately exercising its right of appeal to the U.S. Court of Appeals for the Federal Circuit or first requesting a rehearing before the PTAB. The '393 patent remains valid and enforceable until appeals have been exhausted.

By way of background, the '393 patent claims, among other things, treprostinil produced using an improved method and is listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations publication, also known as the Orange Book, for Remodulin[®] (treprostinil) Injection, Tyvaso[®] (treprostinil) Inhalation Solution, and Orenitram[®] (treprostinil) Extended-Release Tablets. United Therapeutics is currently asserting the '393 patent (along with several other patents) against Watson Laboratories, Inc. and Actavis Laboratories FL, Inc. in connection with their efforts to obtain approval to market generic copies of Tyvaso and Orenitram, respectively. The Watson and Actavis cases are scheduled for trial in September 2017 and February 2018, respectively. SteadyMed, Ltd. initiated the IPR in October 2015, and has reported plans to file for FDA approval of its Trevyent[®] treprostinil product in the second quarter of 2017.

United Therapeutics intends to continue vigorously defending the '393 patent, but even if the ultimate result is unfavorable, United Therapeutics has other patents claiming subject matter similar to the '393 patent and with the same expiration date (December 2028). Specifically, in the last month, the USPTO awarded United Therapeutics two additional patents related to the '393 patent, U.S. Patent Nos. 9,593,066 and 9,604,901. United Therapeutics prosecuted the applications that resulted in these new patents in parallel with the '393 patent IPR and presented claims addressing the invalidity arguments raised by SteadyMed in the IPR and Watson and Actavis in the ongoing litigations. The USPTO allowed the new patent claims with full knowledge of the IPR, the invalidity arguments presented therein, and the invalidity arguments raised by Watson and Actavis in connection with the '393 patent. Thus, United Therapeutics anticipates that these new patents should be less susceptible to challenge than the '393 patent. United Therapeutics has listed both these new patents in the Orange Book for Remodulin, Tyvaso, and Orenitram.

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 possibility of United Therapeutics appealing the PTAB decision, United Therapeutics' intent to continue vigorously defending the '393 patent, United Therapeutics' belief that the two newly issued patents should be less susceptible to challenge than the '393 patent, and the impact of the two newly-issued patents on the timing of market entry for Trevyent. 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, United Therapeutics' plans and ability to defend its intellectual property against challenges from generic companies and from SteadyMed, 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 March 31, 2017, 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.

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