December 20, 2013

FDA Approves Orenitram™ (treprostinil) Extended-Release Tablets for the Treatment of Pulmonary Arterial Hypertension

Conference Call to be Held at 9:00 a.m. Eastern Time, December 23, 2013

SILVER SPRING, Md., Dec. 20, 2013 /PRNewswire/ -- United Therapeutics Corporation (NASDAQ: UTHR) announced today that the United States Food and Drug Administration (FDA) has approved Orenitram (treprostinil) Extended-Release Tablets for the treatment of pulmonary arterial hypertension (PAH) in WHO Group I patients to improve exercise capacity.

"This approval marks the first time that the FDA has approved an orally administered prostacyclin analogue for any disease — and our fifth approval from the FDA for treatment of PAH — supporting our mission of providing a wider choice of PAH therapies for physicians and patients," said Roger Jeffs, Ph.D., United Therapeutics' President and Chief Operating Officer. "We are grateful for the FDA's thorough review and will continue to build clinical support for the use of Orenitram."

The primary efficacy study, FREEDOM-M, demonstrated that patients receiving Orenitram twice daily (BID) improved their median six-minute walk distance (6MWD) by +23 meters [p=0.013] as compared to patients receiving only placebo. As the sole vasodilator, the effect of Orenitram on exercise is small and Orenitram has not been shown to add to other vasodilator therapy. Two other Phase 3 studies (FREEDOM-C and FREEDOM-C^2) did not demonstrate a benefit in exercise with median 6MWD at Week 16 (11 meters [p=0.072] and 10 meters [p=0.089], respectively).

The most common side effects reported in the clinical studies with Orenitram (placebo-corrected incidence > 10%) are headache, nausea, and diarrhea.

Orenitram is dosed twice a day with food, but the total daily dose can be divided and given three times daily with food. Orenitram is available in four strengths: 0.125 mg, 0.25 mg, 1 mg and 2.5 mg. The dose of Orenitram should be increased as tolerated to achieve optimal clinical response. The maximum dose is determined by tolerability.

Conference Call

United Therapeutics will host a half hour teleconference on December 23, 2013, at 9:00 a.m. Eastern Time. The teleconference is accessible by dialing 1-877-351-5881, with international callers dialing 1-970-315-0533. A rebroadcast of the teleconference will be available for one week and can be accessed by dialing 1-855-859-2056, with international callers dialing 1-404-537-3406, and using conference code: 29125503.

This teleconference is also being webcast and can be accessed via United Therapeutics' website at http://ir.unither.com/events.cfm.

About Orenitram

Orenitram is an extended-release tablet for oral administration used to treat PAH, a life-threatening disease that constricts the flow of blood through the pulmonary vasculature. Orenitram contains the same active ingredient (treprostinil) as Remodulin® (treprostinil) Injection and Tyvaso® (treprostinil) Inhalation Solution.

Orenitram is indicated for the treatment of PAH (WHO Group 1) to improve exercise capacity. The primary study that established efficacy (FREEDOM-M) included predominately patients with WHO functional class II-III symptoms and etiologies of idiopathic or heritable PAH (75%) or PAH associated with connective tissue disease (19%). When used as the sole vasodilator, the effect of Orenitram on exercise is about 10% of the deficit, and the effect, if any, on a background of another vasodilator is probably less than this. Orenitram is probably most useful to replace subcutaneous, intravenous, or inhaled treprostinil, but this use has not been studied.

Important Safety Information for Orenitram

- Orenitram is contraindicated for patients with severe hepatic impairment (Child Pugh Class C).
- Abrupt discontinuation or sudden large reductions in dosage of Orenitram may result in worsening of PAH symptoms.

- Orenitram inhibits platelet aggregation and increases the risk of bleeding, particularly among patients receiving anticoagulants.
- Orenitram should not be taken with alcohol as release of treprostinil from the tablet may occur at a faster rate than intended.
- The Orenitram tablet shell does not dissolve. In patients with diverticulosis (blind-end pouches), Orenitram tablets can lodge in a diverticulum.
- Concomitant administration of Orenitram with diuretics, antihypertensive agents or other vasodilators increases the risk of symptomatic hypotension.
- There is a marked increase in the systemic exposure to treprostinil in hepatically impaired patients.
- Co-administration of Orenitram and the CYP2C8 enzyme inhibitor gemfibrozil increases exposure to treprostinil, therefore, Orenitram dosage reduction may be necessary in these patients.
- In the 12-week placebo-controlled monotherapy study, adverse reactions with rates at least 5% higher on Orenitram than on placebo included headache, diarrhea, nausea, flushing, pain in jaw, pain in extremity, hypokalemia, and abdominal discomfort.

For full patient information and full prescribing information, visit:
http://www.unither.com/assets/unither/docs/OrenitramFullPrescribingInformation.PDF.

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 conditions.

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, our intention to continue to build clinical support for the use of Orenitram. These forward-looking statements are subject to certain risks and uncertainties, such as those described in our periodic reports filed with the Securities and Exchange Commission, that could cause actual results to differ materially from anticipated results. Consequently, 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 December 20, 2013, 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]

SOURCE United Therapeutics Corporation