



Trius Therapeutics Obtains Special Protocol Assessment With FDA for Second Phase 3 Study of Torezolid Phosphate

Study Will Examine Efficacy and Safety of IV and Oral Dosing of Torezolid Phosphate in Patients With ABSSSI

SAN DIEGO, Aug. 5, 2011 (GLOBE NEWSWIRE) -- Trius Therapeutics, Inc. (Nasdaq:TSRX) announced today that it has reached agreement with the United States Food and Drug Administration (FDA), under the Special Protocol Assessment (SPA) process, on the design of its second planned Phase 3 study for the intravenous and oral dosage forms of torezolid phosphate for treatment of acute bacterial skin and skin structure infections (ABSSSI). This double-blind pivotal study will compare the efficacy and safety of once-daily administration of 200 milligrams of torezolid phosphate for six days of treatment to twice-daily administration of 600 milligrams of linezolid (Zyvox) for 10 days of treatment. All patients will be initiated on the intravenous dosage (IV) form for a minimum of one day's treatment and will be transitioned to the oral dosage form at the discretion of the clinical investigator. As with the first on-going Phase 3 study testing the oral dosage form, the primary efficacy endpoint of the IV to oral transition study will be the cessation of infected lesion spread and absence of fever at 48 to 72 hours following initiation of treatment. Secondary endpoints will include, among other things, sustained clinical response at the end of therapy visit, and the investigator's assessment of clinical response at all visits and clinical success at the post treatment evaluation visit. Provided non-inferiority is met, an assessment of superiority of torezolid phosphate to linezolid with respect to the primary efficacy endpoint will also be made. Trius expects to start this second pivotal study in the fourth quarter of this year.

Special Protocol Assessment

The SPA process creates a written agreement between the FDA and a sponsor concerning the clinical trial design, clinical endpoints and other clinical trial issues that can be used to support regulatory approval of a drug candidate. The process is intended to provide assurance that if the agreed upon clinical trial protocols are followed, the clinical trial endpoints are achieved and there is a favorable risk benefit profile, the data may serve as the primary basis of an efficacy claim in support of a New Drug Application (NDA).

About Trius Therapeutics

Trius Therapeutics is a biopharmaceutical company focused on the discovery, development and commercialization of innovative antibiotics for serious, life-threatening infections. The company's first product candidate, torezolid phosphate, is an IV and orally administered second generation oxazolidinone being developed for the treatment of serious gram-positive infections, including those caused by MRSA. In addition to the company's torezolid phosphate clinical program, it is currently conducting two preclinical programs using its proprietary discovery platform to develop antibiotics to treat infections caused by bacteria of the gram-negative and gram-positive categories. For more information, visit www.triusrx.com.

This press release contains forward-looking statements regarding Trius' planned activities under the second Phase 3 clinical trial for the IV and oral dosage form of torezolid phosphate. Actual results may differ materially from those in these forward-looking statements. For a further description of the risks associated with these statements, as well as other risks facing Trius, please see the risk factors described in the Company's most recent periodic reports on Form 10-K and 10-Q filed with the United States Securities and Exchange Commission, including those factors discussed under the caption "Risk Factors" in such filings. Forward-looking statements speak only as of the date of this release, and Trius undertakes no obligation to update or revise these statements, except as may be required by law.

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