



Trius Reports Positive Results From First Phase 3 Trial of Tedizolid in Acute Bacterial Skin and Skin Structure Infections

- *Tedizolid over 6 days of therapy achieved all primary and secondary efficacy endpoints versus 10 days of linezolid*
- *Tedizolid demonstrated a lower incidence of adverse events*

SAN DIEGO, Dec. 19, 2011 (GLOBE NEWSWIRE) -- Trius Therapeutics, Inc. (Nasdaq:TSRX) announced today that tedizolid phosphate met the primary objective of non-inferiority for the efficacy outcome of early clinical response versus the comparator linezolid (Zyvox®) in patients with acute bacterial skin and skin structure infections (ABSSSI). Tedizolid also met all secondary efficacy outcomes in this first of two pivotal Phase 3 trials that were designed to support the filing of a New Drug Application (NDA) with the FDA as well as a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA).

The pivotal Phase 3 trial, designated TR701-112, examined the efficacy and safety of a once daily 200 milligram dose of oral tedizolid phosphate over a 6-day course of therapy (followed by four days of placebo) versus a twice daily 600 milligram dose of oral linezolid over a 10-day course of therapy in 667 patients recruited across sites in North America, South America and Europe. In the Intent to Treat (ITT) analysis set, tedizolid achieved the primary objective of non-inferiority (10% non-inferiority margin) to linezolid in the primary and secondary efficacy endpoints.

Top-Line Data from the TR701-112 Trial

ITT Analysis Set		Tedizolid 6 days treatment	Linezolid 10 days treatment
Primary Endpoint	Cessation of spread and absence of fever at 48-72 hours	79.5%	79.4%
Key Secondary Endpoints	Sustained clinical response at end of therapy (Day 10)	69.3% (CE = 80.2%)	71.9% (CE = 81.1%)
	Investigators assessment of clinical response at 7-14 days after end of therapy	85.5% (CE = 94.6%)	86.0% (CE = 95.4%)
Additional Endpoint	greater than or equal to 20% decrease from baseline in lesion area at 48-72 hours	78.0%	76.1%

CE = Clinically Evaluable

Both tedizolid and linezolid were generally well tolerated with comparable overall safety profiles, with drug-related treatment emergent adverse events (TEAE) reported in 24.2% of tedizolid patients versus 31% of linezolid treated patients. Gastrointestinal adverse events were the most commonly reported TEAE, which were statistically significantly lower in tedizolid patients than in linezolid patients (16.3% vs. 25.4%; p=0.004).

"We are very pleased the trial demonstrated that a 6-day course of once daily oral tedizolid is as efficacious as a 10-day course of twice daily oral linezolid while showing an improved tolerability profile," said Jeffrey Stein, Ph.D., President and Chief Executive Officer of Trius. "We look forward to presenting the detailed results of this study, the first Phase 3 study to be conducted under the new regulatory paradigm, both in a peer reviewed journal and at a major conference in 2012."

Trius initiated the second Phase 3 trial of tedizolid phosphate in ABSSSI, designated TR701-113, for its intravenous (IV) to oral transition therapy in September of this year and expects to report top-line data in early 2013. The 113 study is the first clinical trial conducted in collaboration with Bayer HealthCare and will recruit patients in North and South America, Europe, Australia, New Zealand, and South Africa.

Scheduled Conference Call

The Company will host a conference call to discuss the results today, December 19, 2011, at 9:00 a.m. Eastern Time (6:00 a.m. Pacific Time). The conference call may be accessed by calling (877) 845-0779 for domestic callers and (760) 298-5087 for international callers. Please specify to the operator that you would like to join the "Trius Therapeutics Conference Call." The conference call will also be webcast live under the Investors section of Trius' website at <http://investor.triusrx.com>, where it will be archived for 30 days following the call.

About Trius Therapeutics

Trius Therapeutics is a biopharmaceutical company focused on the discovery, development and commercialization of innovative antibiotics for life-threatening infections. The company's lead investigational drug, tedizolid phosphate, is an IV and orally administered second generation oxazolidinone in Phase 3 clinical development for the treatment of ABSSSI. Trius has two Special Protocol Assessments with the FDA for its two Phase 3 ABSSSI trials and has partnered with Bayer HealthCare for the development and commercialization of tedizolid phosphate outside of the U.S. and the European Union. In addition to the company's tedizolid phosphate clinical program, Trius is currently conducting three preclinical programs using its proprietary discovery platform to develop antibiotics to treat infections caused by gram-negative bacteria. For more information, visit www.triusrx.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements, and the results of the 112 study are not necessarily indicative of the results of the 113 study. Such statements include, but are not limited to, statements regarding Trius' ability to successfully complete its ongoing clinical trials and development programs and the expected timing for reporting of top-line data for the TR701-113 study. Risks that contribute to the uncertain nature of the forward-looking statements include: the success and timing of Trius' preclinical studies and clinical trials; regulatory developments in the United States and foreign countries; changes in Trius' plans to develop and commercialize its product candidates; the outcome of final analyses of data from recently-completed clinical trials of tedizolid may vary from Trius' initial analyses and the FDA may not agree with Trius' interpretation of such results; additional ongoing or planned clinical trials of tedizolid may produce negative or inconclusive results; Trius may decide, or the FDA may require Trius, to conduct additional clinical trials or to modify Trius' ongoing clinical trials; Trius may experience delays in the commencement, enrollment, completion or analysis of clinical testing for its product candidates, or significant issues regarding the adequacy of its clinical trial designs or the execution of its clinical trials, which could result in increased costs and delays, or limit Trius' ability to obtain regulatory approval; the third parties with whom Trius has partnered with for the development of tedizolid and upon whom Trius relies to conduct its clinical trials and manufacture its product candidates may not perform as expected; tedizolid may not receive regulatory approval or be successfully commercialized; unexpected adverse side effects or inadequate therapeutic efficacy of tedizolid could delay or prevent regulatory approval or commercialization; Trius' ability to obtain and maintain intellectual property protection for its product candidates; the loss of key scientific or management personnel, Trius' ability to obtain additional financing; and the accuracy of Trius' estimates regarding expenses, future revenues and capital requirements. These and other risks and uncertainties are described more fully in Trius' most recent Form 10-K, Forms 10-Q and other documents filed with the United States Securities and Exchange Commission, including those factors discussed under the caption "Risk Factors" in such filings. All forward-looking statements contained in this press release speak only as of the date on which they were made. Trius undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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