

Trius Announces Positive Results From Phase 2 Clinical Trial of Torezolid in Patients With Complicated Skin and Skin Structure Infections

Second Generation Oxazolidinone Demonstrates Safety and Efficacy with Once-Daily, 200 milligrams (mg) Dosing over Five to Seven Days of Treatment

SAN DIEGO, June 8, 2009 -- Trius Therapeutics, Inc. today announced results from its Phase 2 clinical trial evaluating the safety and efficacy of oral torezolid (TR-701), its investigational antibiotic for the treatment of severe complicated skin and skin structure infections (cSSSI) caused by gram-positive bacteria, especially drug-resistant strains such as methicillin-resistant *Staphylococcus aureus* (MRSA). The study achieved its primary goals of establishing safety and efficacy in all doses evaluated.

In the randomized, double-blind, dose-ranging study conducted at eight centers in the U.S., torezolid was administered orally at doses of 200, 300 or 400 mg once-daily for five to seven days of treatment. Of the 188 patients who received drug, 164 (87%) were clinically evaluable at the test-of-cure visit. The overall cure rates of clinically evaluable patients for severe abscesses, cellulitis and wound infections were 96%, 97% and 90%, respectively. Clinical outcomes were not affected by the size of lesions. Clinical cure rates by dose in the clinically evaluable population were 98%, 94% and 94% for the 200, 300 and 400 mg doses, respectively. In the group of microbiologically evaluable patients (133, 71%), clinical cure was achieved in 100%, 93% and 96% of patients receiving 200, 300 or 400 mg doses, respectively. There were no clinical relapses at the late follow-up visit 21-28 days post treatment. Highlighting the growing problem of drug resistance in the community, MRSA was the primary pathogen in 72% of the microbiologically evaluable patients.

“I was impressed by the rapid clinical effect of oral torezolid in curing severe skin infections caused by MRSA and other gram-positive pathogens,” said Dr. Joseph Surber, Chief Medical Officer, Southeast Regional Research Group, Columbus, GA, a clinical investigator of the Phase 2 study. “The nature of such infections usually warrants use of an IV antibiotic, but the trial results indicate that oral torezolid successfully treated these severe infections quickly and effectively.”

“We set strict severity criteria for enrollment to ensure that patients had a clear need for systemic antibiotic therapy,” said Philippe Prokocimer, M.D., Chief Medical Officer of Trius. “Two-thirds of the patients treated had systemic signs of infection, such as fever or elevated white blood cell counts. The fact that the lowest dose of 200 mg was as efficacious as the higher doses also provides for a broad safety margin. In our prior 21-day Phase 1 clinical trial, which examined hematological parameters as key markers of oxazolidinone safety, the 200 mg dose of torezolid was comparable to placebo while the labeled dose of linezolid produced the expected depletion of platelets and other cell lines. It is also encouraging that the efficacy of the 200 mg dose in patients is consistent with the dose predictions based on animal efficacy studies. Collectively, these data enable us to select the 200 mg dose for our Phase 3 pivotal trials in complicated skin and soft tissue infections.”

Torezolid was well tolerated by patients in this Phase 2 trial. Treatment-emergent adverse events related to study drug, 92% of which were assessed as mild, occurred in 35%, 52% and 50% of subjects in the 200, 300 and 400 mg dose groups, respectively. Importantly, there were no study discontinuations due to adverse events. Laboratory results showed no significant shifts from baseline in hematology or chemistry parameters, including platelets or liver enzymes.

“The efficacy and safety of torezolid in this trial demonstrate its potential for the rapid treatment of severe infections caused by *Staph aureus*, including MRSA, in both the community and the hospital,” said Jeffrey Stein, Ph.D., Chief Executive Officer of Trius. “Later this year we will complete Phase 1 testing of the IV dosage form of torezolid and plan to merge the oral and IV programs in Phase 3 testing early next year. Our aim is to make torezolid available to physicians and patients as soon as possible to address the growing unmet medical need for an effective and well tolerated new IV and oral treatment for drug-resistant infections.”

About Torezolid (TR-701)

Torezolid is a second-generation IV/oral antibacterial drug in the oxazolidinone class. It is significantly differentiated from Zyvox® (linezolid), the only marketed drug in this class. Advantages of torezolid over linezolid include:

- 4-8 fold greater potency than linezolid in vitro and in vivo
- In vivo bactericidal activity
- Activity against all clinically important, gram-positive, drug-resistant strains including those resistant to linezolid
- Activity against clinically important atypical and gram-negative pathogens (*Legionella*, *Chlamydia*, *Neisseria*)
- 16x lower rate of resistance development in MRSA
- Once-daily and shorter course of therapy to promote better treatment compliance
- Broader safety window enabling potential longer course of therapy
- Possibility for expanded indications including bacteremia, severe CAP and osteomyelitis
- Lower potential for drug-drug interactions including those with dietary tyramine, SSRIs and vasoconstrictors

About Trius Therapeutics

Trius Therapeutics is discovering and developing innovative antibacterial drugs for the treatment of infections caused by drug-resistant pathogens. The company’s lead drug candidate, torezolid, is a second generation oral and IV oxazolidinone antibiotic with potent activity against drug-resistant, gram-positive bacterial pathogens including those resistant to linezolid, the only currently marketed antibacterial drug of the oxazolidinone class. Trius’ pipeline includes two preclinical programs with lead candidates for serious infections caused by gram-negative bacterial pathogens. For more information, visit www.triusrx.com.

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