



### **Rib-X Pharmaceuticals Announces Positive Phase 2 Study Results for Delafloxacin and a \$25 Million Financing**

*—Novel Fluoroquinolone Demonstrates Safety and Efficacy in Treatment of Skin Infections*

**NEW HAVEN, CONNECTICUT. JANUARY 26, 2009** — Rib-X Pharmaceuticals, Inc., a development stage company focused on the discovery, development and commercialization of novel antibiotics for the treatment of antibiotic resistant infections, today announced positive final results from a Phase 2 clinical trial of its novel fluoroquinolone antibiotic, delafloxacin (RX-3341), in the treatment of complicated skin and skin structure infections (cSSSI).

Separately, Rib-X today also announced that the company closed on a \$25 million financing, which will fund the ongoing development of its pipeline of novel antibiotics. This round included participation from all of Rib-X's major investors, including: Warburg Pincus, ABS Ventures, Axiom Ventures, EuclidSR Partners, MedImmune Ventures, Oxford Bioscience Partners, S.R. One, and Vox Equity Partners I.

In the double-blind study, delafloxacin was administered intravenously at two different doses, 300 mg twice daily (BID) and 450 mg BID; the comparator was tigecycline (TYGACIL®, Wyeth Pharmaceuticals), the only broad spectrum agent recently approved (2005) by the FDA for use in cSSSI. Delafloxacin showed comparable efficacy and improved tolerability relative to tigecycline at the FDA-approved dosing regimen for this indication. In the clinically evaluable population, the cure rates for delafloxacin 300 mg BID and 450 mg BID were 97.2% and 92.5%, respectively, while the cure rate for tigecycline was 91.2%.

*Staphylococcus aureus* was the most frequently isolated pathogen, accounting for approximately 85% of all pathogens collected. Approximately 70% (68/96) of the *S. aureus* isolates were methicillin-resistant (MRSA) and 63% of the MRSA were levofloxacin resistant. MIC<sub>90</sub> values for delafloxacin, tigecycline, and levofloxacin against all *S. aureus* isolates were 0.06, 0.12, and 4 micrograms/mL, respectively.

Delafloxacin's MIC90 values against all MRSA including the quinolone-resistant MRSA strains was also 0.06 micrograms/mL.

"We are extremely encouraged by the final results of this third Phase 2 trial, which affirm delafloxacin's safety and show its broad spectrum activity in difficult-to-treat complicated skin infections," said Susan Froshauer, Ph.D., President and CEO of Rib-X Pharmaceuticals. "Delafloxacin proved to be the more active compound compared to tigecycline when evaluated against both Gram-positive and Gram-negative bacterial isolates from patients, including MRSA and quinolone-resistant MRSA and other organisms. Additionally, this drug has the potential for IV use in the hospital with an oral step down."

"Rib-X starts off 2009 extremely well positioned to proceed with advancing delafloxacin towards Phase 3 trials," continued Dr. Froshauer. "We not only have excellent Phase 2 results for one of our key compounds, but we also have the commitment of our investors, and we would like to thank them for their continued support."

**PHASE 2 STUDY DESIGN AND RESULTS**

This Phase 2 double-blind study evaluated the safety and efficacy of delafloxacin at two intravenous doses, 300 mg BID and 450 mg BID, compared to tigecycline (TYGACIL®, Wyeth Pharmaceuticals), in adults with cSSSI. Treatment duration was 5 to 14 days. Of the 150 patients randomized in this trial, 68% were male; the mean age was 40+/-14.5 years. 36% had cellulitis, 31% had wound infections and 33% had abscesses. 111 (74%) patients had pathogens identified at baseline, with 96 identified as *S. aureus*. The clinical cure rates in the Clinically Evaluable and Modified Intent-to-Treat populations are presented below:

Population	Percent Clinical Cure at TOC		
	DFX 300 mg BID	DFX 450 mg BID	TIG 50 mg BID
Clinically Evaluable	97.2% p = 0.35*	92.5% p = 1.00*	91.2%
Modified Intent-to-Treat	89.8% p = 0.39*	90.2% p = 0.26*	82.0%

\*p value for comparison between DFX and TIG group

In this trial, delafloxacin was safe and well tolerated. Lower rates of overall treatment-related adverse events were noted in both 300 mg BID and 450 mg BID dose groups compared to tigecycline. The most common adverse events reported in the trial were mild and gastrointestinal in nature. Specifically, delafloxacin had notably lower rates of nausea and vomiting as compared to tigecycline

### **PRIOR CLINICAL TRIALS WITH DELAFLOXACIN**

The oral formulation of delafloxacin has been evaluated in two successful Phase 2 studies. In one study, delafloxacin was effective at doses as low as 200 mg once daily in patients with community-acquired pneumonia (CAP). In the second study, conducted in patients with acute bacterial exacerbation of chronic bronchitis (ABECB), delafloxacin, at a once a day dose of 200 mg for 5 days, was as efficacious as levofloxacin, 500 mg once daily for 7 days.

### **ABOUT CSSSI**

Complicated skin and skin structure infections encompass a wide range of serious infections involving the deeper soft tissue, including severe cellulitis and major abscesses. These infections may occur in patients with skin ulcers or burns, as well as patients who have undergone surgery or experienced other kinds of trauma. These infections affect over one million patients in the U.S. annually and are most commonly caused by Gram-positive bacteria, specifically *Staphylococcus aureus* and methicillin-resistant

### **ABOUT DELAFLOXACIN**

Delafloxacin is a novel, broad spectrum, next-generation fluoroquinolone, that is more active than other quinolones against Gram-positive bacteria, including isolates of MRSA that are resistant to other quinolones. In large panel microbiological testing, the compound has been shown to be at least 32-fold more potent than levofloxacin, ciprofloxacin, gatifloxacin and moxifloxacin against quinolone-resistant MRSA (MIC<sub>90</sub> of less than or equal to 0.5 micrograms/mL for delafloxacin versus > 16 micrograms/mL for all other quinolones). Currently in development as an intravenous formulation, delafloxacin has also been shown to be more potent than existing quinolones against a

range of Gram-positive, anaerobic and Gram-negative organisms. Rib-X is interested in developing both IV and oral formulations of delafloxacin for use in surgical prophylaxis and other therapeutic arenas within the over \$9.9 billion hospital antibiotic market.(1) ant *S. aureus* (MRSA).

**ABOUT RIB-X PHARMACEUTICALS, INC.**

Rib-X Pharmaceuticals, Inc. is a product-driven small molecule drug discovery and development company focused on the structure-based design of new classes of antibiotics. The Company's underlying drug discovery engine capitalizes on its proprietary high-resolution crystal structure of the ribosome, which performs an essential role in protein synthesis. Many known, commercially valuable antibiotics exert their effects by binding to the bacterial ribosome. The Company's integrated research strategy, which combines state-of-the-art, proprietary computational analysis, X-ray crystallography, medicinal chemistry, microbiology and biochemistry, allows it to rapidly synthesize new agents designed to avoid typical antibiotic resistance mechanisms. Rib-X's iterative intelligent engine has yielded several distinctive new antibiotics that can be used for the treatment of either community- or hospital-acquired infections. In addition to delafloxacin, Rib-X is currently in Phase 2 trials with radezolid (RX-1741), an oxazolidinone that was discovered at Rib-X, as an oral/IV agent for treatment of serious Gram-positive infections. The R<sub>X</sub>-04 discovery program is developing novel classes of antibiotics active against multi-drug resistant Gram-negative bacteria and the R<sub>X</sub>-02 discovery program is focused on developing an IV/oral macrolide active against methicillin-resistant *S. aureus*, multidrug-resistant *Streptococcus pneumoniae* and *S. pyogenes*. Both delafloxacin and radezolid are currently in Phase 2 clinical trials.

(1) Commercial and Pipeline Insight: Hospital Antibacterials - A market beyond MRSA; Datamonitor; August 24, 2007

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