

Affinium Pharmaceuticals, Ltd., Announces First Patient Dosed with Oral AFN-1252 in a Phase 2 Clinical Trial for Acute Bacterial Skin & Skin Structure Infections

Austin, Texas and Toronto, Ontario, February 1, 2012 — Affinium Pharmaceuticals announced today dosing of the first patient in a multi-center Phase 2 clinical trial evaluating oral AFN-1252 in acute bacterial skin & skin structure infections (“ABSSSI”). The Phase 2 trial is the first human efficacy study conducted with this new class of antibiotic and follows the recently completed Phase 1 trials which demonstrated excellent safety, tolerability and pharmacokinetics of AFN-1252 in single and multiple ascending oral dosages.

The Phase 2 study will confirm efficacy and tolerability of 200 mg of oral AFN-1252 dosed twice daily for 5-14 days in patients with staphylococcal skin infections. The trial will also evaluate both the traditional endpoints at end of treatment and early endpoints currently recommended by the FDA.

“We’re on the cusp of delivering human proof-of-concept data for our antibiotic, AFN-1252, with its truly new mechanism of action and unique selective spectrum. Preclinical animal data indicates AFN-1252 has mg/kg efficacy that is significantly improved compared to linezolid; and both single and multiple dose Phase 1 data indicate an excellent safety and tolerability profile. We are confident that the Phase 2 trial will confirm AFN-1252 as a potent and well tolerated anti-Staph antibiotic” commented Dr. Hafkin, Chief Medical Officer of Affinium Pharmaceuticals.

According to Leisa Dennehy, Commercial & Corporate Development Advisor at Affinium, “market research with physicians clearly indicates the need for an IV and oral antibiotic with an improved safety profile compared to vancomycin or linezolid, without compromising potency against MRSA. We believe AFN-1252 will provide physicians with a compelling alternative to vancomycin or linezolid in the treatment of known or suspected MRSA infections for patients where vancomycin or linezolid safety risks cannot be tolerated. Additionally, an oral MRSA agent offers a potential pharmacoeconomic advantage by treating patients at home with a safe and potent oral agent, rather than treating in the hospital or out-patient clinic with IV antibiotics.”

Each year in the US, there are more than ten million patient visits for treatment of skin infections. *Staphylococcus* is the mostly commonly identified pathogen in skin infections and is a potential pathogen in almost every infection type, making staphylococci the most common pathogen in a large and diverse patient population. “A staphylococcal-specific antibiotic provides the unique benefits of no off-target effects on gut flora and no resistance selection pressure on other bacterial species which greatly reduces the probability of antibiotic associated adverse events such as *C. difficile* disease, diarrhea or candidiasis, while providing high potency against the desired target”, remarked Nachum Kaplan, Ph.D, Vice President of Microbiology at Affinium. “AFN-1252 is like no other antibiotic ever developed, and we look forward to having the Phase 2 data later this year.”

About Affinium Pharmaceuticals

Affinium Pharmaceuticals is a specialty pharmaceutical company focused on the development of novel anti-infective medicines. The Affinium fatty acid synthesis (“FASII”) antibacterial programs constitute a new antibiotic franchise with the potential for multiple patented products targeting the FASII pathway in various bacteria.

About AFN-1252

AFN-1252, the lead clinical candidate from Affinium’s FASII program, is designed to selectively target the staphylococcal FabI enzyme. AFN-1252 provides exceptional nanomolar potency against all drug-resistant phenotypes of staphylococci, including hospital- and community-acquired methicillin-resistant *Staphylococcus aureus* (MRSA) and coagulase-negative staphylococci. Extremely low propensity for microbial resistance development has been observed in microbiological studies. The antibiotic has also shown excellent *in vivo* efficacy in animal models of infection. Oral bioavailability and excellent safety & tolerability have been demonstrated in four Phase 1 clinical trials and in human microdosing studies. The oral formulation is in Phase 2 and an injectable formulation is in late pre-clinical development. .

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