

Affinium Pharmaceuticals, Ltd., Announces Results of AFN-1252 Multiple Ascending Dose Phase I Clinical Trial

Austin, Texas, May 2, 2011 — Affinium Pharmaceuticals announced today the results of a new multiple ascending dose Phase I study of its novel, selective-spectrum, anti-staphylococcal agent, AFN-1252 in a novel oral formulation.

The study examined the tolerability, safety and pharmacokinetics of immediate release tablets of AFN-1252. Cohorts of healthy volunteers were dosed 200mg, 300mg, and 400 mg of AFN-1252 once daily for 10 days.

The pharmacokinetic results indicate that doses of either 300 mg, and 400mg, once daily or 200 mg twice daily, met or exceeded exposures necessary for the treatment of serious staphylococcal infections. Most importantly, and as in all previous Phase 1 trials, AFN-1252 showed a very favorable safety profile for all doses studied with no treatment-related trends in clinical laboratory results including biochemistry and hematology, vital sign measurements, 12 lead ECG results, or physical examination findings. Adverse events reported in the study were limited to mild headache and mild nausea.

Barry Hafkin MD, Chief Medical Officer of Affinium Pharmaceuticals, commented, “These results support our belief that AFN-1252 will provide a unique and improved efficacy and safety profile over currently available anti-staphylococcal antibiotics. Almost all antibiotics have significant safety concerns and a new oral and IV product with the potential for solid efficacy and safety is critically needed to treat suspected or confirmed staphylococci infections.”

“We are very excited about the unique position that AFN-1252 can have in the future competitive landscape” said Leisa Dennehy, Affinium Commercial & Corporate Development. “Market research with US physicians shows a strong interest in a selective-spectrum antibiotic targeting staphylococci. Selectively in spectrum suggests there will be a lower propensity for disrupting normal flora and associated adverse events, and will eliminate resistance pressure on other bacteria. The incredible potency against all strains of staphylococci combined with the potential safety advantages creates a uniquely desirable medical product. Given that there are tens of millions of staphylococcal infections annually, we believe the market for a staphylococci-specific drug is very attractive.”

“This MAD study has met our high expectations and supports moving ahead with the development of AFN-1252 as a potent once-a-day or twice a day oral antibiotic for serious infection.” said Dr. Hafkin. In the second half of 2011, Affinium will initiate a Phase II clinical study of oral AFN-1252 in acute bacteria skin and skin structure infections.

About Affinium Pharmaceuticals

Affinium Pharmaceuticals is a specialty pharmaceutical company focused on the development of novel anti-infective medicines. The Affinium FASII antibacterial programs constitute a new antibiotic franchise with the potential for multiple products targeting the FASII pathway. These programs include a broad base of long-term intellectual property: issued and pending composition of matter patents on potent orally available small molecule inhibitors of a new class of antibiotics with a unique mechanism of action, targeting an underexploited pathway.

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. An injectable formulation is advancing through pre-clinical development.

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