

AUSTIN, TX and TORONTO, ON, Nov. 12, 2013 /PRNewswire/ - Affinium Pharmaceuticals ("Affinium") announced today that the U.S. Food and Drug Administration (FDA) has designated Affinium's Phase 2 antibiotic, AFN-1252, as a Qualified Infectious Disease Product (QIDP) for use in acute bacterial skin and skin structure infections (ABSSSI) based on the Phase 2 study recently completed in that indication. The QIDP designation is expected to enable Affinium to benefit from FDA regulatory incentives for new antibiotics, including priority review, and a five year extension of new chemical entity exclusivity.

"We are very pleased to receive the QIDP designation for our ground-breaking staphylococcal-specific antibiotic, AFN-1252", says Dr. Ed Mascioli, Chief Executive Officer of Affinium. "It provides important acknowledgment that *Staphylococcus* continues to be a major pathogen with significant unmet needs."

In addition, Affinium today announces that it has completed dosing of the planned IV Phase 1 single ascending dose study of AFN-1720, the prodrug of AFN-1252. All planned cohorts for the Phase 1 study were dosed and results will be available in the coming weeks.

About AFN-1720 and AFN-1252

AFN-1720 is a new prodrug of Affinium's successful clinical-stage drug, AFN-1252, and represents a new clinical-stage agent in this novel class of antibiotics. Due to the unique, staphylococcal-specific spectrum of AFN-1252, AFN-1720 is expected to preserve the human gut microbiome resulting in minimal antibiotic-associated side effects, such as antibiotic-induced diarrhea or *C. difficile* overgrowth. Clinical data observed to date support this concept. Additionally, with no resistance pressure on other bacterial species, the development of multiple drug-resistant organisms like vancomycin-resistant enterococci (VRE) is unlikely. Oral and IV AFN-1720 are being developed for clinical use in several serious infections. AFN-1252, the parent molecule of AFN-1720, is 3-20 times more potent than linezolid in animal models of infection, and is exquisitely potent against all strains of

Staphylococcus aureus

, with an MIC

90

of 0.016 µg/ml against 5,400 strains of

Staphylococcus aureus

tested to date including all known resistant strains such as MRSA and vancomycin-intermediate S.

aureus

(VISA). In clinical trials, AFN-1252 has demonstrated an excellent efficacy, safety and tolerability profile in over 250 subjects.

About Staphylococcal Infections

Staphylococcus is the mostly commonly identified bacterial pathogen in man and is a potential pathogen in almost every type of bacterial infection. Methicillin-resistant strains of S.

aureus

(MRSA) account for about half of all S.

aureus

strains in the US and cause significant morbidity and mortality worldwide. According to the Infectious Disease Society of America (IDSA), MRSA kills more Americans every year than emphysema, HIV/AIDS, Parkinson's Disease and homicides combined.

About Affinium Pharmaceuticals

Affinium Pharmaceuticals is a clinical-stage biopharmaceutical company focused on the development of novel anti-infective medicines based on bacterial fatty acid synthesis inhibition. The antibacterial program constitutes a new antibiotic platform with the potential for multiple patented products inhibiting bacterial fatty acid synthesis in several different bacterial species.

SOURCE Affinium Pharmaceuticals