

Novexel's NXL104/ceftazidime Combination Commences Phase II Clinical Trial in Hospital Patients with complicated Urinary Tract Infections

Paris, France, November 12, 2008 -- Novexel, a speciality pharmaceutical company focused on the discovery and development of novel antibiotics designed to overcome the significant global problem of microbial resistance, announces today that its most advanced injectable antibacterial, which combines Novexel's broad spectrum beta-lactamase inhibitor, NXL104, with the well established cephalosporin antibiotic, ceftazidime, has entered Phase II clinical trials.

The initial Phase II trial with NXL104/ceftazidime will be in hospitalized patients with complicated urinary tract infections (cUTIs). From national databases providing hospital patient discharge data¹, Novexel estimates that more than 1.1 million patients were treated for cUTIs in the hospital in the seven major pharmaceutical markets in 2007. NXL104/ceftazidime is being developed to treat hospital infections that are caused by Gram negative bacteria, including those resistant to many currently used antibiotics.

This Phase II trial is a prospective, multicenter, investigator-blinded, randomized study which is designed to evaluate the efficacy, safety, and tolerability of NXL104/ceftazidime vs. imipenem cilastatin (Primaxin® or Tienam®, Merck & Co. Inc., NYSE: MRK) in the treatment of adults with cUTIs. Complicated urinary tract infections include acute pyelonephritis, UTI in men, or UTI associated with obstruction, foreign bodies, or urologic abnormalities. A total of approximately 150 patients will be enrolled, with 75 patients being included in each treatment arm.

The primary objective of the study is to evaluate the microbiological response to NXL104/ceftazidime in the treatment of adult patients with cUTIs as compared to imipenem/cilastatin. This evaluation will be based on the Test of Cure visit five to nine days post-therapy. After at least 4 days of IV antibiotic therapy, patients may be switched to oral ciprofloxacin, if they meet protocol-defined criteria. The total duration of antibiotic therapy for each patient should be 7 to 14 days. The results of this study are expected in late 2009.

In completed Phase I studies in healthy subjects NXL104/ceftazidime was generally well tolerated and the pharmacokinetics of the two components were well matched. Additional studies in special populations are ongoing.

Iain Buchanan, Novexel's CEO, said, "We continue to believe that this novel combination, which is based around our novel beta-lactamase inhibitor, NXL104, has the potential to play an important role in confronting the increasing problem of hospital infections caused by resistant Gram negative bacteria. The start of our first Phase II study with NXL104 in combination with ceftazidime is an important milestone for the company."

Under an independent development program, Forest Laboratories (NYSE : FRX) will combine NXL104 in a treatment regimen with Forest's ceftaroline, a novel, bactericidal injectable broad spectrum cephalosporin being developed as a therapeutic agent for the treatment of gram-positive pathogens including methicillin resistant staphylococcus aureus (MRSA), and multi-drug resistant streptococcus pneumoniae (MDRSP), as well as common gram-negative organisms. Ceftaroline is being studied as a monotherapy in Phase III clinical

trials by Forest. In January 2008, Novexel granted Forest a license to develop, manufacture and commercialise NXL104, only in combination with ceftaroline, in North America.

Novexel retains worldwide rights on the NXL104/ceftazidime combination.

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About NXL104

NXL104 is a novel injectable non beta lactam, beta-lactamase inhibitor, which is being developed to address the increasing problem of microbial resistance to beta lactam antibiotics (penicillins, cephalosporins, carbopenems) mediated by beta-lactamase enzymes. NXL104 is a significant advance, as it is able to inhibit a broader range of beta-lactamases than currently marketed beta-lactam inhibitors. Its spectrum includes class A (including ESBL and KPC) and class C enzymes. NXL104 in combination with ceftazidime will be targeting infections caused by Gram negative bacteria, including Enterobacteriaceae and Pseudomonas.

About Novexel

Novexel is a speciality pharmaceutical company focused on the discovery and development of novel anti-bacterials designed to overcome the significant global problem of bacterial resistance. The ever increasing resistance to marketed antibiotics has led to a clear need for novel drugs that are active against multi-drug resistant bacteria. Novexel's products are targeting the global hospital antibiotic market, which was worth an estimated \$15bn in 2007 according to information derived from the IMS Midas® database.

Novexel currently has two novel antibacterials in Phase II clinical development. These are the injectable beta-lactamase inhibitor, NXL104, which is being developed in combination with the cephalosporin antibiotic ceftazidime for serious Gram negative infections, and the oral streptogramin antibiotic, NXL103, for the treatment of Gram positive infections, with a focus on treatment in the hospital setting and intravenous (IV) to oral switch. Novexel has three further programmes in preclinical development, NXL105, a novel anti-Pseudomonal antibiotic, NXL201, a novel echinocandin antifungal agent, and NXL104 in combination with ceftaroline. This latter product is being developed by our partner, Forest Laboratories, solely for North American markets.



Novexel was created in December 2004 as an independent spin-out of the sanofi-aventis (Euronext Paris: SAN, NYSE: SNY) anti-infectives unit. Novexel has a team of 50 employees with significant experience in anti-infective research and development, who are located in Paris, France and Philadelphia, USA.

ⁱ USA: HCUPnet; France, Agence technique de l'Information sur l'Hospitalisation ; UK The Information Center (Hospital Episode Statistics) ; Germany, Federal Health Monitoring; Spain, Eurostat; Italy & Japan: OECD.