Novexel's NXL104/ceftazidime Combination Commences Second Phase II Clinical Trial in Hospital Patients with complicated Intra-Abdominal Infections (cIAIs)

Paris, France, March 3, 2009 -- 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 a second Phase II clinical trial.

This Phase II trial with NXL104/ceftazidime will be in hospitalized patients with complicated intra-abdominal infections (cIAIs). In 2007, Novexel estimates that more than 300,000 patients were treated for cIAIs in hospital in the seven major pharmaceutical markets. This estimate is based on national databases providing hospital patient discharge data.

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, double-blind, randomized study which is designed to evaluate the efficacy, safety, and tolerability of NXL104/ceftazidime plus metronidazole vs. meropenem (Merrem® or Meronem®, AstraZeneca, NYSE:AZN) in the treatment of adults with cIAIs. Complicated intra-abdominal infections include those infections requiring surgical intervention and which extend beyond the hollow viscus into the peritoneal space. A total of approximately 200 patients will be enrolled, with 100 patients being included in each treatment arm.

The primary objective of the study is to evaluate the clinical response to NXL104/ceftazidime plus metronidazole in the treatment of adult patients with cIAIs as compared to meropenem. This evaluation will be based on the Test of Cure visit two weeks post-therapy. The total duration of antibiotic therapy for each patient should be 5 to 14 days. The results of this study are expected in early 2010.

This second Phase II trial in cIAIs, follows a Phase II clinical trial of NXL104/cetazidime in hospitalized patients with complicated urinary tracts infections (cUTIs). This study which began in November is due to complete 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, "The start of this second Phase II study demonstrates Novexel's commitment to developing NXL104 in combination with ceftazidime in a broad range of indications where resistant Gram negative bacteria are present or are suspected. NXL104 has the ability to inhibit the activity of a broader range of clinically important beta-lactamases than currently marketed beta-lactam inhibitors and we believe that this combination product could provide an important new treatment option in the hospital."

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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. Ceftaroline is 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 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 antibiotics designed to overcome the significant global problem of microbial 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.

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