

## **Novexel presents 16 posters and one slide presentation at the 49<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) meeting in San Francisco**

**Paris, France, 11 September 2009** – Novexel, a specialty pharmaceutical company focused on the discovery and development of novel antibiotics designed to overcome the significant global problem of microbial resistance, announces that its pipeline will be the subject of 16 posters and one slide presentation at the 49<sup>th</sup> annual meeting of the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC). The ICAAC meeting, which is taking place in San Francisco, California, September 12-15 2009, is the leading global conference on anti-microbial agents globally with over 10,000 participants.

The posters presented at the conference cover:

- NXL103, a novel oral streptogramin, which has completed a successful Phase II study in patients with community acquired pneumonia (CAP). It has been shown to be highly active against methicillin resistant *Staphylococcus aureus* (MRSA) and will soon start a Phase II trial in complicated Skin and Skin Surface infections (cSSSIs).
- NXL104, Novexel's broad spectrum non- $\beta$ -lactam class A and C  $\beta$ -lactamase inhibitor which, in combination with the cephalosporin antibiotic ceftazidime, is currently in two Phase II trials for complicated urinary tract infections (cUTIs) and complicated intra abdominal infections (cIAls).

### **NXL103**

NXL103 is the subject of 6 posters.

Poster L1-336 covers a Phase II trial which compared NXL103 with amoxicillin in the treatment of mild to moderate community acquired pneumonia (CAP) in adults. The trial showed that 500mg or 600mg of NXL103 twice a day was efficacious in the treatment of CAP and produced similar results to high dose amoxicillin. NXL103, which was generally well tolerated, may be an effective oral therapy for CAP and based on its spectrum, for complicated skin and skin structure infections (cSSSI).

Posters A1-1944, A1-1945 and A1-1946 cover the Phase I work with NXL103 and show that the product was generally well tolerated, that it shows a beneficial interaction with food, and that no dosing adjustment was required in elderly patients. Poster A1-1943 looks at the optimization of the ratio of linopristin and flopristin, the two components of NXL103. This study concludes that a dose consisting of 250mg of linopristin and 350mg of flopristin is optimal as it gives lower pharmacokinetic variability and delivers optimal ex-vivo plasma bactericidal activity in all subjects.

Poster E-1965 provides data on the *in vitro* activity of NXL103 against MRSA. The study concludes that NXL103 is highly active against important bacterial species of cSSSIs including community acquired MRSA and hospital acquired MRSA, supporting the further

development of this novel streptogramin for indications such as cSSSI, where staphylococci are important pathogens.

## **NXL104**

NXL104, either alone or in combination with ceftazidime, is the subject of 9 posters and one slide presentation.

Poster A1-007 covers a Phase I study in healthy volunteers looking at the effects of age and gender on the pharmacokinetics of NXL104. The study shows that NXL104 is well tolerated and that no dose adjustment is required based on age or gender.

Poster C1-1374 describes the nature of inhibition of the class A TEM-1  $\beta$ -lactamase by NXL104. Slide Presentation C1-1098 describes the high resolution crystal structure of NXL104 complexed with the extended spectrum  $\beta$ -lactamase CTX-M-15 to understand the molecular details of mechanism of inhibition.

Three of the posters outline research with NXL104/ceftazidime in murine models of infection. Poster A1-006 shows that the NXL104/ceftazidime is efficacious in a pneumonia model using a strain of *Klebsiella pneumoniae* expressing elevated levels of AmpC  $\beta$ -lactamase. Poster B-1339, shows that NXL104/ceftazidime is very effective in two murine models of infection against a strain of *Klebsiella pneumoniae* harboring the KPC carbapenemase, which has been shown to confer resistance to all other  $\beta$ -lactams and  $\beta$ -lactamase inhibitor combinations. Poster A1-005 shows that NXL104/ceftazidime has good parenteral efficacy against *Enterobacteriaceae* bearing a CTX-M  $\beta$ -lactamases in a mouse septicemia model. In all three models, ceftazidime alone has poor activity.

The remaining 4 posters cover *in vitro* studies with NXL104/ceftazidime. Poster E-194 shows that the combination was active against 300 geographically diverse clinical isolates of *Pseudomonas aeruginosa* while Poster E-186 shows that it had a broad spectrum of activity against resistant *Enterobacteriaceae* isolates. Poster E-188 and Poster E-192 examines the activity of NXL104/ceftazidime against anaerobic bacteria. In these last two posters the combination, together with metronidazole, is shown to have potent anti-anaerobe activity against most clinical anaerobe species, making it potentially useful in the treatment of mixed infections.

## **NXL104/ceftaroline**

A final poster sponsored jointly by Novexel and Forest (B-1339a) shows the efficacy of ceftaroline combined with NXL104 against ceftaroline-resistant organisms in a mouse septicemia model. All posters will be available for download from Novexel's web site ([www.novexel.com](http://www.novexel.com)) shortly after the close of ICAAC.

In addition to these Novexel sponsored posters, 4 posters will be presented by Forest Inc on NXL104 in combination with ceftaroline. Forest licensed North American rights to develop and commercialize NXL104 solely in combination with ceftaroline in January 2008. Novexel retains rights to the NXL104-ceftazidime combination worldwide, including in North America.

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**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 \$17bn in 2008.<sup>1</sup>

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 Novexel's partner, Forest Laboratories (NYSE: FRX), 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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<sup>1</sup> Source: IMS Health, MIDAS, 2006-2008