



## **Nabriva initiates Phase II of pleuromutilin antibiotic BC-3781**

*First patient enrolled in Phase II study of BC-3781 in patients with acute bacterial skin and skin structure infections (ABSSSI)*

**Vienna, Austria- 2 June 2010-** Nabriva Therapeutics today announced that the first patients have been enrolled in a Phase II clinical trial of BC-3781 in acute bacterial skin and skin structure infections. BC-3781 is a pleuromutilin antibiotic being developed for the treatment of bacterial diseases such as skin and skin structure infections and pneumonia.

The Phase II clinical study is a double blind study with two doses of BC-3781, using vancomycin as a comparator and designed to establish safety, tolerability and efficacy of BC-3781. BC-3781 is being administered intravenously in this study. The study will enroll 210 patients and will be conducted in 20-25 sites in the USA.

Dr William Prince, CMO Nabriva Therapeutics commented:

"This is the first patient study with a systemic pleuromutilin. It will be an important proof of concept for an exciting new class of antibiotics. The phase II study builds on our extensive preclinical and phase I data which have demonstrated that BC-3781 can achieve therapeutically relevant blood and tissue levels in man with excellent tolerability when administered by either oral or intravenous routes."

Dr. David Chiswell, CEO Nabriva Therapeutics commented:

"With a worldwide problem due to antibiotic resistant bacteria, there is a very significant need for new classes of antibiotics with unique modes of action such as the pleuromutilins. The commercial prospects for BC-3781 as the leading compound of an exciting new class are excellent, especially as it has an ideal anti-bacterial spectrum for both skin and respiratory infections and is being developed with both oral and intravenous formulations"

BC-3781 is highly active against key pathogens, including MRSA, associated with skin infections and community and hospital acquired pneumonia and is more potent than Linezolid and vancomycin. The compound's novel mode of action ensures that it overcomes resistance mechanisms affecting all approved classes of antibiotics. BC-3781 is the first pleuromutilin antibiotic to be developed for both oral and intravenous use in humans.

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### **About Nabriva Therapeutics**

Nabriva Therapeutics is a biotechnology company focused on developing a new class of antibiotics for the treatment of serious infections caused by resistant pathogens. Nabriva's lead systemic product, BC-3781, is being developed for the treatment of serious skin infections and bacterial pneumonia caused by *S. aureus*, *S. pneumoniae*, *H. influenza*, *Mycoplasma*, *Legionella* and other bacteria, including drug resistant strains such as MRSA and vancomycin resistant *E. faecium*. In addition, Nabriva Therapeutics' topical pleuromutilin product candidate, BC-7013, is in clinical phase I. Nabriva Therapeutics has a proven track record in world-class medicinal chemistry, clinical expertise, a seasoned management team and solid IP. Nabriva Therapeutics is located in Vienna, Austria.

For more information on Nabriva please visit [www.nabriva.com](http://www.nabriva.com).

**Notes for editors:**

**BC-3781**

The pleuromutilin BC-3781 belongs to the first generation of pleuromutilins to combine excellent oral and intravenous bioavailability BC-3781 is highly active against multi-drug resistant (MDR) pathogens including methicillin resistant *Staphylococcus aureus* (MRSA), MDR *Streptococcus pneumoniae* (i.e. macrolide and quinolone resistance), and vancomycin resistant *Enterococcus faecium*. It is characterized by excellent *in vivo* activities, outstanding PK/PD parameters, and a novel mode of action. BC-3781 is being developed for both oral and IV administration and is intended for the treatment of serious multi-drug resistant skin & skin structure infections (ABSSSI) and moderate to severe pneumonia (CAP, HAP).

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