Nabriva Reports Positive Results from Phase II Trial of Pleuromutilin Antibiotic BC-3781 in ABSSSI

First proof of concept for systemic use of this new class of antibiotics in man

Vienna, Austria- 18 April 2011- Nabriva Therapeutics today announced the successful results of a Phase II clinical trial of BC-3781 in acute bacterial skin and skin structure infections (ABSSSI). Nabriva's lead product BC-3781 is the first of a new class of systemically available pleuromutilin antibiotics for the treatment of serious skin infections and pneumonia. BC-3781 is being developed for both oral and intravenous formulations.

This double blind, randomized controlled study compared two doses of BC-3781, with Vancomycin, the standard treatment for drug resistant Gram-positive bacterial skin infections, in 207 patients with ABSSSI recruited in 23 centers in the USA. BC-3781 had the same efficacy as Vancomycin, using both the traditional Test of Cure and newer early endpoints, and was safe and well tolerated. The results of this study provide the first proof of concept for the use of a pleuromutilin antibiotic systemically in man.

Dr William Prince CMO commented:
"The results are excellent; especially considering this study is the first to treat patients with a pleuromutilin administered intravenously. The patient population selected for this study was severely ill and each had two signs of systemic disease. The results confirm the efficacy of BC-3781 in skin infections. It is also significant that BC-3781 was well tolerated and that there was no evidence of clinical safety concerns since one of the persistent barriers to the development of new classes of antibiotics has been the issue of patient safety."

Dr. David Chiswell, CEO Nabriva Therapeutics added:
"These encouraging results are an important milestone for Nabriva and our plans to establish intravenous and orally administered pleuromutilins as a new class of antibiotics. We are now moving forward with plans to conduct phase III studies using both oral and intravenous administration in two indications: ABSSSI and hospital treated community-acquired pneumonia (HCAP)."

About the study
The double blind randomized active controlled study was conducted at 23 centers in the USA and compared two doses of BC-3781 with Vancomycin. In 207 patients with ABSSSI who received 100mg or 150mg of BC-3781 or 1,000mg Vancomycin intravenously twice-daily. All patients had at least two signs of systemic infection (e.g. fever, raised level of white blood cells, C-reactive protein or lymphadenopathy). Approximately 50% of the patients had cellulitis and approximately 30% had abscesses with cellulitis. The average area of cellulitis was more than 160cm^2. 60% of the ITT (intention to treat) population were microbiologically evaluable and of those 69% had documented MRSA infection.

The results show that both doses of BC-3781 were comparable to Vancomycin in terms of clinical response at the primary end point, test-of-cure:

- 90% of the patients (54/60) treated with 100mg of BC-3781,
- 89% of the patients (48/54) treated with 150mg of BC-3781,
- 92% of the patients (47/51) treated with 1000mg of Vancomycin.

In addition, following the recent FDA guidance, the early clinical response was assessed using a composite endpoint (cessation of spread of erythema with a lack of fever) at day 3:

- 83% of patients achieving this endpoint with 150 mg BC-3781
- 86% of patients achieving this endpoint with 100mg BC-3781
- 80% of patients achieving this endpoint with Vancomycin

BC-3781 showed an excellent safety profile and was well tolerated. No drug related serious adverse events (SAE) were recorded for BC-3781 in any arm. BC-3781 at both doses showed lower incidences of drug related treatment emergent adverse events (TEAEs) compared to Vancomycin.

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*.

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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. 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's current shareholders include: Phase4 Ventures HBM Partners, The Wellcome Trust, Global Life Science Ventures, Novartis Venture Fund and Sandoz. Nabriva Therapeutics is located in Vienna, Austria.

For more information on Nabriva please visit www.nabriva.com.

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Notes for editors:

About 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 pneumonia* (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).