



Nabriva completes recruitment for Phase II of pleuromutilin antibiotic BC-3781

US Phase II study of BC-3781 in patients with acute bacterial skin and skin structure infections (ABSSSI)

Vienna, Austria- 10 January 2011- Nabriva Therapeutics, a biotechnology company focused on developing a new class of antibiotics for serious infections caused by resistant pathogens, today announced that it has completed recruitment of a Phase II clinical trial of BC-3781 in acute bacterial skin and skin structure infections (ABSSSI). BC-3781 is a pleuromutilin antibiotic with both oral and intravenous dose forms that is being developed for the treatment of bacterial diseases such as skin and skin structure infections and pneumonia.

210 patients have been recruited from 24 clinical sites in the USA. This Phase II clinical study was a double blind study with two dose regimens of intravenous BC-3781 (100 or 150mg twice daily) versus vancomycin as an active comparator. The primary endpoint of the study was to assess the clinical response to these two dose regimens. Secondary endpoints, in line with the recent FDA guidance on trials of ABSSSI, included the cessation of spread of lesions within 48-72 hours and the resolution of fever.

Dr. David Chiswell, CEO of Nabriva Therapeutics commented: "BC-3781 has now been tested in 10 clinical trials involving over 370 subjects/patients in both oral and intravenous dose forms. Assuming the Phase II data is positive this data package should allow us to take BC-3781 forward into an extensive Phase III program."

Dr. William Prince, CMO of Nabriva Therapeutics added: "In designing this trial we included the endpoints proposed in the recent draft FDA guidance on developing drugs for the treatment of ABSSSI. We expect to have top line data available during the first quarter of 2011. The ultimate intention is to seek FDA and EMA approval for the treatment of bacterial skin and lung infections as well as other indications offering both intravenous and oral formulations of BC-3781."

BC-3781 is highly active against key pathogens, including MRSA, associated with skin infections and community and hospital acquired pneumonia. The compound's novel mode of action ensures that it overcomes antibiotic resistance developed due to the use of 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 *Staphylococcus aureus*, *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, *Legionella pneumophila*, *Mycoplasma* and *Chlamydia* spp. including drug resistant strains such as MRSA and vancomycin resistant *E. faecium*. 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.

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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