NABRIVA THERAPEUTICS ANNOUNCES QUALIFIED INFECTIOUS DISEASE PRODUCT AND FAST TRACK STATUS GRANTED BY THE US FDA FOR LEFAMULIN

Vienna / Philadelphia, 8 October 2014: Nabriva Therapeutics AG, a biotechnology company focused on developing pleuromutilins, a new class of antibiotics for the treatment of serious infections caused by resistant Gram-positive and Gram-negative pathogens, announced today that the United States Food and Drug Administration (FDA) has granted Qualified Infectious Disease Product (QIDP) as well as Fast Track status designation to Nabriva's lead product lefamulin, for the treatment of community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI).

The FDA's Fast Track program allows an expedited review facilitating the development of drugs and biologics intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. The QIDP designation allows five extra years of market exclusivity for antimicrobials designed to treat serious and life-threatening infections. These designations have been granted to lefamulin used for the treatment of CABP and ABSSSI. It is estimated that five to 10 million cases of CABP in the US lead to 1.1 million hospitalizations and 45,000 deaths annually. ABSSSI are among the most common infections requiring hospitalization and exert a substantial burden on the health care system.

Dr Colin Broom, Chief Executive Officer of Nabriva, commented on the news: "There is a serious and growing public health threat as a result of the rise in increasingly difficult-to-treat bacterial infections. The FDA's QIDP and Fast Track designations are validation of Nabriva's approach and underlying science to develop a truly novel antibiotic product able to address significant unmet need. Nabriva is establishing its US office and clinical development team in Philadelphia and is focussed on advancing lefamulin to phase 3 trials, for an initial indication in CABP."

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Notes to editors
About Nabriva Therapeutics AG
Nabriva Therapeutics is a biotechnology company focused on developing a new class of antibiotics, the pleuromutilins, for the treatment of patients with serious infections caused by multi-drug resistant pathogens. Nabriva's world-class medicinal chemistry expertise has achieved an industry first with the development of both intravenously administered and orally available pleuromutilins that are therefore ideal for i.v. to oral switch therapy.

Nabriva's lead product lefamulin (BC-3781) is about to enter Phase 3 clinical studies. Due to its broad spectrum, oral and i.v. formulations, and a favourable safety profile, lefamulin is the first of a new

class of antibiotics ideally positioned for the treatment of community-acquired bacterial pneumonia (CABP), plus hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP), as well as acute bacterial skin and skin structure infections (ABSSSI), with potential in several other indications (sexually transmitted infections including MDR gonorrhoea; osteomyelitis) including paediatric use.

Nabriva's preclinical program, the Extended Spectrum Pleuromutilins (ESP) expands the activity of pleuromutilins to include major enteric Gram-negative pathogens such as *E. coli* and *K. pneumoniae*. The targeted indications for the ESP extend beyond the current use of the first-generation pleuromutilins, thereby filling important gaps in treatment options of both marketed antibiotics and compounds in development.

About CABP and ABSSSI

Community acquired bacterial pneumonia (CABP)
Community-acquired respiratory tract infections, especially community-acquired bacterial pneumonia (CABP), represent one of the main causes of morbidity and mortality among children and adults. CABP is a commonly occurring serious infection that requires systemic antibiotic therapy and is associated with considerable healthcare costs. The dominant bacterial causes are *Streptococcus pneumoniae* and *Haemophilus influenzae*, accounting for more than 80 % of CABP cases. Furthermore, a significant proportion of CABP cases are caused by the 'atypical agents', mainly *Mycoplasma pneumoniae, Chlamydophila pneumoniae* and *Legionella pneumophila*. CABP is the most frequently occurring infectious disease and the sixth most common cause of death in the U.S. and a leading cause of death worldwide. The emergence of CABP pathogens resistant to antimicrobials, the emergence of severe necrotizing pneumonia with high morbidity and mortality associated with CA-MRSA and the limited pipeline of new antibiotics in development underscore the critical need for new antimicrobial agents for the treatment of CABP.

Acute bacterial skin and skin structure infections (ABSSSI)
Complicated skin and skin structure infections (cSSSI) or ABSSSI include, among others, infections of deeper soft tissues, cellulitis, wound infections, burns, and major abscesses. Gram-positive bacteria, in particular *Staphylococcus aureus*, *Streptococcus pyogenes* and *Streptococcus agalactiae* are the most common pathogens in ABSSSI. Of increasing concern is the rapidly rising frequency of ABSSSI caused by methicillin-resistant *S. aureus* (MRSA) and there has been a dramatic increase in the occurrence of community-acquired MRSA (CA-MRSA). In most U.S. cities CA-MRSA is now the most common pathogen cultured from patients with skin and skin structure infections in emergency departments.