# ASX Release

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## Positive result for Avexa's Antibacterial Program in Animal Proof of Concept Studies

Australian biotechnology company Avexa (ASX: AVX) today announced positive results from animal model proof of concept studies on its lead compound AVX13616 given topically for the treatment of drug-resistant bacterial infections. Highly potent antibacterial activity was demonstrated against a strain of bacteria that is resistant to a wide range of antibiotics. This activity was observed at concentrations of compound that could be easily achievable in the clinic. AVX13616 is a completely new class of synthetic antibiotic with rapid bacterial killing activity.

AVX13616 was tested in an animal model in which the bacterial growth of methicillin resistant Staphylococcus aureus (MRSA) in the nasal linings is measured. Human nasal linings are a common reservoir for these superbugs in hospital environments. The multi-drug resistant MRSA strain used in Avexa's model was isolated from such an environment. The model was conducted at a Maryland based (USA) independent contract research organization. The technical background section (see below) describes the results in more detail.

"This is a significant increase in the value of this program as it shows that it can target the bacteria that cause serious hospital infections" said CEO Dr Julian Chick. "We are excited by the results and the progress we have made in this program."

The applications for such an antibacterial drug would encompass a wide range of skin infections including impetigo, infected burn wounds, and catheter related bacterial infections (a significant number of which result in serious bacterial blood infections). The National Institutes of Health (NIH) estimate that the annual cost of treating all antibiotic-resistant infections in the United States may be as high as $30 billion.

MRSA has been increasing in significance as a hospital-acquired pathogen in Australia since the 1980s. MRSA infection, especially when acquired in a hospital setting, can result in a serious and life threatening illness. These infections are often treated initially with vancomycin. However, vancomycin-resistant Staphylococcus is also increasing.

Avexa will continue to progress the program, including the optimization of an intravenous version of the lead compound. The company is also interested in looking at opportunities to enter into a licensing agreement with a suitable partner.

**For more information**:

Dr. Julian Chick
Chief Executive Officer
+61 (03) 9208 4300

Mr. Rod North
Bourse Communications
+ 61 (03) 9510-8309

www.avexa.com.au

**Avexa Limited is a Melbourne-based biotechnology company with a focus on research and development of drugs for the treatment of infectious diseases, in particular diseases which have a significant unmet medical need. Avexa has dedicated resources and funding for key projects including antiviral drugs for HIV/AIDS and an antibiotic alternative for antibiotic-resistant bacterial infections. The company's lead program is apricitabine which is currently in Phase IIb clinical trials. Recruitment for the Phase IIb trial is due for completion by the end of 2006 and the results due in the 1st quarter 2007.**

## Technical background

The original aim of the project (in collaboration with the University of Wollongong) was to develop a drug that would be able to treat bacteria that had become resistant to vancomycin, often referred to as an antibiotic of 'last resort'. However, detailed in-vitro studies on this class of compounds revealed a unique spectrum of activity against not only vancomycin-resistant bacteria but also many resistant forms of Staphylococcus aureus – in particular two of the most common superbugs, methicillin resistant Staphylococcus aureus (MRSA) and methicillin resistant Staphylococcus epidermidis (MRSE). MRSE is associated with infections of intravenous devices, renal dialysis catheters and orthopedic prostheses.

The model was conducted at a Maryland based (USA) independent contract research organization and Avexa had no direct input into the conduct and analysis of the study results.

The following graph shows that at the higher concentrations AVX13616 significantly decreases the levels of bacteria that are able to colonize the nasal linings. Bacterial counts were determined three days after the last dose of AVX13616. The diluted doses were applied by intranasal administration twice a day for 5 days in a similar way that current intranasal therapies are used. In comparison the undiluted dose of AVX13616 was applied once only and caused a large and significant decrease in the amount of bacteria measured 3 days after the final administration of AVX13616. If these preclinical results were directly extrapolated to the clinic, such a single dose treatment has potential advantages for topical intranasal applications where current treatments are twice a day over a 5 to 10 day period.