



## **ASX Release**

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### **Avexa gets 'all clear' from Phase I cardiac safety trial**

Avexa (ASX:AVX) announced today results from the first of its two current Phase I studies for apricitabine. The results showed that apricitabine had no significant adverse effect on cardiac safety, thereby demonstrating a safe cardiac profile. Apricitabine is a novel nucleoside reverse transcriptase inhibitor (NRTI) being developed for the treatment of HIV infection. In line with current FDA guidelines this study was required by the FDA as part of the apricitabine development plan and thus is another positive step towards clearance for Phase III trials for apricitabine. The Phase I trial was carried out in the USA.

The Phase I cardiac safety study examined the potential for apricitabine to cause changes in the heart rhythm, a side effect which is known to occur with some other drugs and which can, in rare cases, have serious consequences.

The analysis involved studying thousands of heart rhythm traces from 37 healthy volunteers dosed with apricitabine and showed no significant effect of apricitabine upon the heart rhythm, even at doses in excess of those used in the current clinical programme, supporting the positive safety profile of apricitabine. The study made use of an adaptive design, a new approach in clinical trial design which seeks to maximize the outcome of clinical trials whilst minimizing the duration, cost, and risk to participants.

"This demonstration of cardiac safety for apricitabine in this Phase I study further emphasizes the safety profile of apricitabine and is an important milestone in its continued development," said Dr Chick, CEO. "This clears another step in the path towards Phase III trials for apricitabine".

The establishment of adequate cardiac safety for new drugs in development has become an important regulatory requirement prior to Phase III development. Although previous pre-clinical and clinical studies with apricitabine have not shown any evidence of effects on the heart, current guidelines recommend completion of a specific, thorough cardiac safety trial for new drugs in late stage development.

#### **Technical data**

This Phase I trial was a double blind, placebo controlled study. It also included a positive control in a randomized cross over study design. The study investigated the cardiovascular safety of apricitabine. 37 healthy subjects were randomized to receive apricitabine and its matching placebo in one of two sequences: apricitabine first then placebo, or placebo first then apricitabine. Moxifloxacin, a drug known to have an effect on cardiac function was included in the study as a positive control.

**A V E X A**

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At doses of apricitabine in excess of the dose currently used in clinical trials, the mean placebo-corrected change in the individual corrected QT interval (QTcI) from baseline ranged from -0.5 to 6.0 msec, with the 90% upper confidence bound ranging from -3.03 to 8.36 msec in different analyses. These changes fall within a range considered of no clinical significance, and therefore apricitabine is unlikely to present any risk of cardiac arrhythmia at doses in excess of those currently used in clinical trials. In comparison, for the positive control moxifloxacin the mean change ranged from 2.37 to 11.15 msec with a 90% upper confidence bound ranging from 6.05 to 15.72 msec. The full results of this study will be presented at a scientific conference in 2007.

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**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 1<sup>st</sup> quarter 2007.**