



## **ASX Release**

### **Avexa's Phase I trial shows ATC has potential for combination therapy with Tipranavir**

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Avexa (ASX: AVX) today announced results from a further Phase I study for apricitabine (ATC). The results showed that ATC can be dosed with tipranavir without any significant reduction in plasma levels of ATC and that it should therefore be possible to co-dose ATC and tipranavir in the future. ATC is a novel nucleoside reverse transcriptase inhibitor (NRTI) being developed by Avexa for the treatment of HIV infection. This Phase I study was required by the FDA as part of the apricitabine development plan and thus is another positive step towards Phase III trials for apricitabine.

Tipranavir is a recently approved protease inhibitor that is used to treat HIV-infected patients in combination with drugs from other classes such as NRTIs. Previously published data has shown that tipranavir significantly reduces the plasma levels of some other NRTIs (such as AZT and abacavir), which can lead to reduced antiviral activity for the combination of drugs. The study was therefore undertaken to establish whether tipranavir would have a similar effect on apricitabine.

The study was carried out in the USA and involved 18 healthy volunteers. It examined the potential for tipranavir to affect the plasma levels of ATC when ATC and tipranavir were dosed together. The study involved measuring plasma drug levels in healthy volunteers dosed with ATC alone or in combination with tipranavir. The results show that tipranavir does not result in a significant reduction in the plasma levels of ATC when the two drugs are co-dosed. "Combination therapy is the name of the game in the effective treatment of HIV/Aids. This demonstration that ATC can be dosed together with tipranavir without any significant reduction in ATC drug levels is a further step forward for ATC, and shows a potential clinical advantage of ATC compared to a number of other NRTIs," said Dr Chick, CEO. "Completing this trial is another step forward for ATC as it progresses through clinical development".

HIV patients are commonly treated with a drug cocktail comprising several different drugs from different classes. Not all HIV drugs can be safely and effectively used together. "Our earlier pre-clinical data indicates that ATC is well suited for combination with other HIV drugs, and these data support and extend this expectation" stated Dr Chick. The ability of apricitabine to be easily combined with other HIV medications is an important advantage which helps to simplify treatment choices, for both physicians and patients alike.

#### **Technical data**

This Phase I trial was an open label, controlled, intra subject comparison of the pharmacokinetics of apricitabine when dosed alone or in combination with tipranavir. 18 healthy subjects were administered oral doses of apricitabine alone, or in combination with tipranavir. Plasma samples were taken following dosing and pharmacokinetic parameters estimated.



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At doses of tipranavir currently used in the treatment of HIV, the maximum plasma concentration (C<sub>max</sub>) and area under the concentration-time curve (AUC) for apricitabine were approximately 1.25 and 1.4 times that for apricitabine dosed alone, respectively, which is not considered to be clinically relevant. 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 (ATC) which is currently in Phase IIb clinical trials. Recruitment for the Phase IIb trial was completed in December 2006 and the results are due in the 1<sup>st</sup> quarter of 2007.**