



ASX Release

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Update on apricitabine's Clinical Development

Avexa Limited (ASX: AVX) announced an update on the clinical progress of apricitabine, its novel anti-HIV drug. The clinical strategy remains focused on undertaking three clinical trials in concert to facilitate the development and commercialization of this promising antiretroviral drug.

Completion of dosing phase of two Phase I trials.

Avexa has completed the dosing phase of its two Phase I trials. These two studies are important steps in the development of apricitabine. The first trial studied the effect of apricitabine on heart function, and the second studied the potential for adverse effects when apricitabine is co-dosed with the newly marketed protease inhibitor tipranavir. In the first study an adaptive design was used which significantly reduced the number of subjects required and allowed the accelerated completion of the study. Adaptive design is a new technique in clinical trials which enables early information from a trial to be used to enhance study outcomes, but without reducing the overall power of the study to reach its endpoints. Both studies were reviewed by the FDA prior to commencement and were carried out in the USA under the IND for apricitabine in healthy volunteers.

Avexa enrolled 37 volunteers into the heart function trial and 18 volunteers into the tipranavir co-dosing trial. Importantly, no serious adverse effects were noted in either trial which is most encouraging as high doses of apricitabine were used in these trials. This observation underscores the excellent safety profile of apricitabine. "Analysis of data from both trials is underway, and results will be released to the market soon" said Avexa CEO Dr Julian Chick.

Phase IIb trial progress.

Avexa reports that recruitment of drug-resistant HIV-infected patients into its Phase IIb is progressing. In response to the initially disappointing recruitment rate Avexa has opened a further three clinical trial sites in Argentina and will continue to open further sites in Argentina. In addition a number of sites in Chile and the USA are being pursued to ensure recruitment numbers for the trial are met, and also to start preparation for the Phase III campaign.

As previously signalled in April, Avexa has now started its Phase IIb extension study. In this extension study patients enrolled into the original Phase IIb trial can elect to continue taking apricitabine after they complete the 48 week treatment period of that trial. Essentially this extension phase gives patients the opportunity to continue to receive apricitabine where it appears that they are receiving benefit from the drug. The extension trial will in turn provide Avexa with long term safety data and information on the durability of patients' response to apricitabine.

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About Avexa Limited

Avexa Limited is an Australian based biotechnology company with a focus on research and development of anti-infectives. The company is developing drugs for the treatment of infectious 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. Additionally, Avexa has programs targeting HIV and drug resistant bacterial infections.