



## ASX Release

DATE: Monday July 24 2006

### Update on Apricitabine's Development Novel Treatment for HIV in Three Clinical Trials

Avexa Limited (ASX: AVX) today announced guidance on the clinical progress of apricitabine, its novel anti-HIV drug. The clinical strategy remains focused on operating three clinical trials in concert to facilitate meeting regulatory criteria and establishing a commercial roadmap for this promising antiretroviral. In addition to the Phase IIb trial for apricitabine already in progress, the Company has also initiated a Phase I cardiac safety study and a co-dosing Phase I trial with tipranavir.

To date, five patients in the Phase IIb trial have successfully completed the 24 week blinded stage of treatment and moved into the open label part of the protocol, in which they receive 800 milligrams of apricitabine, twice daily as part of their therapy. Several of these patients have already been in the open label period for 10 weeks or longer. As per the trial protocol, patients will continue treatment for up to 24 weeks unless their therapy ceases to be effective in controlling viral load, or adverse effects precluded continued dosing with apricitabine. Avexa remains encouraged as the therapy appears to be well tolerated and continues to be effective in these particular treatment resistant patients.

As reported in March of this year, recruitment for the Australian trial sites has been slow due to the strict inclusion criteria for HIV treatment resistant patients and the emergence of other late stage infectious disease drug trials at sites within Australia. As a result recruitment for the Phase IIb is ongoing and will need to continue beyond the mid-year time frame. In response, Avexa has taken actions to increase the enrollment rates by initiating trial sites in Argentina and by modifying the inclusion criteria to include double class experienced patients as well as triple class experienced HIV patients. Thus far, seven sites in Argentina have been opened resulting in a significant increase in enrollment, and the identification of a number of additional eligible patients for entry into the trial.

While there is inherent unpredictability to clinical trial timelines, the Company estimates that the Phase IIb trial will be completed by the end of the 4th quarter of 2006.

"It is important to note that in developing treatments for HIV, Phase IIb trials represent the essential component in transitioning drugs from purely speculative to therapeutic viability. This is the time to enforce comprehensive development protocols to ensure expeditious regulatory processing and ultimately, patient benefit." said Julian Chick PhD, Avexa's Chief Executive Officer

The FDA mandates that all antiretroviral candidates conduct cardiac safety studies. Avexa's Phase I cardiac safety study is well underway and expected to be finished on time and on budget.



The Phase I co-dosing trial with tipranavir has been initiated and has received the go-ahead for patient enrollment. Tipranavir is a promising new protease inhibitor, and the co-dosing of tipranavir and apricitabine has the potential to expand clinicians' HIV armamentarium. This study is expected to be completed within the next few months.

Avexa had AUD \$20 million in cash at 30 June 2006, which is sufficient funding to deliver the results from the Phase IIb and both Phase I trials.

#### Phase III preparations

Initial feedback from regulatory authorities indicates that it may be possible for the Company to file for approval after 24 weeks dosing in the Phase III trial rather than the usual 48 week dosing period. This benefit stems from apricitabine's ability to target a broader range of HIV drug-resistant strains.

Moving forward, the Company will be consulting with international regulatory authorities to determine the appropriate strategy to complete apricitabine's clinical development. As part of the Phase III preparation process, Avexa is planning for the manufacture of the requisite quantities of apricitabine and the acquisition of likely comparator drugs that may be required in the blinded trial.

The company is hosting a conference call on Wednesday, July 26th at 9:00 AM EST to review the material stated in this release and to provide additional information and commentary on apricitabine's clinical and commercial development roadmap.

Below is the dial-in information for Investors interested in participating:

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#### About Avexa

[www.avexa.com.au](http://www.avexa.com.au)

Avexa Limited is a Melbourne-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. The company also has exciting programs targeting HIV and drug resistant bacterial infections.