



## ASX/Media Release

**Monday, 25 July 2005**

### **Avexa begins Phase IIb trial of HIV drug: Shareholder update**

Research and development biotechnology company Avexa (ASX: AVX) today announced that the international Phase IIb trial of its lead HIV compound – AVX754 – is now underway. The trial is aimed at patients who are failing their current HIV therapy.

“Since in-licensing AVX754 from Shire Pharmaceuticals earlier this year the team at Avexa has been working hard to prepare the Phase IIb trial,” said Dr Julian Chick, Avexa’s Chief Executive Officer. “AVX754 is an exciting project for the company and we want to keep shareholders fully informed about this study. We are on track and expect to have results from this trial in the first quarter of 2006.”

AVX754 is a nucleoside reverse transcriptase inhibitor. The Phase IIb trial is investigating the effect of AVX754 on the level of virus in HIV patients that have been treated with existing HIV therapies but are failing these therapies. The enrolment target for this study is 60 patients. This clinical trial design has been successfully reviewed by both the US Food and Drug Administration (FDA) and Australian Ethics Committees. The trial is being conducted under the AVX754 investigational new drug status (IND) held by Avexa as well as local regulatory requirements.

Patients will be dosed initially for 21 days, followed by a further period of dosing to 24 weeks. This trial design will provide the company with both early proof-of-concept data and also longer term safety data to support the planned Phase III studies.

“We set ourselves an aggressive timeline to initiate the Phase IIb by July and we have achieved this,” said Dr Chick, “This has only been possible because of the strength of Avexa’s team and the expertise within the company.”

Avexa’s management has a track record in taking drugs to market. It has previously been involved in the successful development of a first-line therapy HIV drug as well as an anti-herpes drug that is used by HIV patients.

According to figures published by UNAIDS/WHO in December 2004, it is estimated that 39.4 million people around the world are living with HIV/AIDS. Last year alone it is estimated that 4.9 million people became infected with HIV. UNAIDS predicts that in the Asia Pacific region alone there could be up to 12 million new HIV infections between 2005 and 2010.

#### **About Avexa**

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 AVX754, in-licensed from Shire in January 2005.

#### **For more information:**

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