



ASX/Media Release

FDA feedback and expert panel review positive for Avexa

Tuesday, 4th October 2005

Research and development biotechnology company Avexa Limited (ASX: AVX) announced that, following a meeting with the US Food and Drug Administration (FDA), it has received encouraging feedback on the development plan for its HIV/AIDS drug candidate AVX754. This places the Company in an excellent position to move rapidly into Phase III after the successful completion of its ongoing Phase IIb trial.

Avexa expects to have results on the primary endpoint of its Phase IIb trial in the first quarter of calendar year 2006.

Additionally, Avexa met with an international panel of independent, world-renowned experts in the clinical management of HIV to discuss the potential AVX754 may offer in the treatment of patients with drug-resistant HIV who are failing their current therapy. The panel also discussed the ongoing Phase IIb trial for AVX754 and the Company's planned Phase III development programme.

"The feedback Avexa has received from the FDA and from key opinion leaders in the field indicates that successful completion of our Phase IIb trial should allow us to move directly into a Phase III programme," said Avexa Chief Executive Officer, Dr Julian Chick. "This endorsement further validates the expertise within the Company. In addition, our Phase III development plan is clear, focussed and able to deliver a straightforward path to market."

"These discussions reinforce our belief that there is an increasing medical need for second-line treatments for HIV, and that AVX754 is well placed to fulfil that need and capture a significant market opportunity. We believe we are on-track to launch in 2009, a new NRTI [nucleoside reverse transcriptase inhibitor] offering hope for patients failing first-line HIV therapies," said Dr Chick.

Avexa is planning to present to investors in London at the BioPartnering conference later this month and at a New York investor conference in November.

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About Avexa

Avexa Limited is an ASX-listed 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 is focused on developing therapies for the treatment of HIV/AIDS and other viral diseases, and an antibiotic alternative for antibiotic-resistant bacterial infections. The Company recently in-licensed the Phase II stage drug, AVX754, from the global specialty pharmaceutical company Shire Pharmaceuticals Group. Avexa is currently undertaking Phase IIb trials on AVX754 with results expected in the first quarter of 2006. Avexa has followed the ASX Code of Best Practice for Biotechnology Companies in preparing this announcement.