



ASX Release

Avexa ramps up Phase III preparations for AVX754

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Research and Development biotechnology company Avexa Ltd (ASX:AVX) today reported its progress with the ongoing AVX-201 Phase IIb trial and its intentions to ramp up preparations towards Phase III development.

The AVX-201 Phase IIb trial is a blinded study of the efficacy of AVX754 in the treatment of drug-resistant HIV infection. Although the study is blinded as to the exact treatment an individual receives, no person enrolled into the trial to date has experienced any adverse effects attributed to the study treatment. No subjects have been withdrawn from the study, and the first subject has completed 6 months of dosing.

Although recruitment of patients into the Phase IIb trial has been slower than originally anticipated, Avexa has implemented a number of actions to speed enrolment and boost the progress of the clinical trial. In the first quarter of this year Avexa moved quickly to nearly double the number of clinical trial sites involved in the trial. Avexa has also increased its clinical trial presence in Argentina to expedite recruitment.

"The slower than expected recruitment has for the most part been due to the very strict criteria set for this important investigation into the antiviral activity against drug-resistant HIV" said Dr Julian Chick, CEO of Avexa. "Avexa has responded quickly to accelerate recruitment towards completion, and is confident that it has taken all appropriate steps to ensure continued progress of the trial."

The primary endpoint of the trial is the reduction in the amount of virus in the blood after three weeks treatment. Avexa is aiming to complete enrolment by mid-year.

Avexa also announced today its intention to ramp up its preparations towards Phase III development of AVX754 following completion of the Phase IIb trial. The company is preparing to increase a number of activities - including scale up of manufacturing capabilities, production of sufficient quantities of study drug for Phase III, and regulatory activities prior to initiating Phase III trials - as well as taking on extra staff. "These increased activities are necessary now to pave the way for Phase III development, and ensure that Avexa can move quickly into Phase III as soon as possible." said Dr Chick.

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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 infections, and an antibiotic alternative for antibiotic-resistant bacterial infections. The company's lead program is AVX754, in-licensed from Shire in January 2005.