

**A V E X A**

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## Press Release

### AVEXA CLOSING ATC'S PHASE III TRIAL TO EVALUATE DATA

**Melbourne, Australia, 2nd October 2009: Avexa Limited (ASX:AVX)** today announced that the apricitabine (ATC) Phase III study will be closed and the data will be subsequently unblinded and analysed. After extensive interaction with the regulatory authorities and potential partners, the decision was made to evaluate the 24 week data with the results due in the first quarter of 2010.

The 24 week data will provide important information on ATC when used together with other anti-HIV drugs normally used to treat HIV infection, especially those recently approved. Depending on the result, these data may clarify ATC's role in modern treatment regimens and determine the potential for ATC's use in combination therapy. Analysis of these data may lead to a more rapid path to regulatory filing.

"The unblinding of our Phase III trial is a critical period in the development of ATC," said Dr. Julian Chick, Chief Executive Officer. "The rationale for closing the trial, which was expected to run through 2011, was based on two key factors. First, the results may offer key insight into ATC's role in the overall HIV treatment landscape and discussions with regulatory authorities may clarify the ATC approval path. Secondly, this will allow for a mature enough data point to enable potential partners the ability to make a definitive decision on the licensing of ATC."

Avexa's Phase III trial has been conducted with more than 130 sites worldwide and compares ATC to 3TC in drug-resistant HIV patients. In June 2009, Avexa announced that the Data and Safety Monitoring Board had reviewed the Phase III trial and determined the lower 800mg dose was preferred for the continuation of the trial. At this point, the trial continued with two arms comparing the 800mg ATC dose to 3TC. All patients who enrolled in the 16-week dose determination arm have now completed 24 weeks of treatment. In addition, patients from the earlier Phase IIb study, which used the 800mg ATC dose, have been successfully treated with ATC for up to three years. This provides further evidence of the safety, efficacy, and durability of 800mg ATC for the treatment of HIV.

#### **About apricitabine (ATC)**

Apricitabine (ATC) is an anti-HIV nucleoside reverse transcriptase inhibitor (NRTI). ATC is Avexa's lead program and has successfully completed the 96 week dosing of its Phase IIb clinical trial and commenced its Phase III trials worldwide in January 2008 in HIV patients with NRTI resistance. In clinical trials to date, ATC has shown the following characteristics: a unique resistance profile over 96 weeks of treatment, continued efficacy beyond two years of treatment, an excellent safety profile, and an ongoing immunological benefit. Dr Jonathan Coates, Avexa's Chief Scientific Officer, is a former Project Leader for multiple anti-viral programs at GlaxoSmithKline and a co-inventor of anti-viral drug 3TC, one of the best selling anti-HIV drugs in history with over USD \$8 billion in global sales to date. ATC targets a current unmet medical need that has earned the compound Fast Track status with the FDA.



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### **About Avexa**

Avexa Limited is a Melbourne-based biotechnology company with a focus on discovery, development and commercialization of small molecules for the treatment of infectious diseases. Avexa has dedicated resources and funding for key projects including apricitabine (ATC), its HIV integrase program, its HCV polymerase program and an antibiotic program for antibiotic-resistant bacterial infections.

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