

**A V E X A**

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## Press Release

### POSITIVE OUTCOME REACHED AT 16 WEEKS FOR AVEXA'S ATC PHASE III TRIAL

- **DSMB recommends continuation of the ATC Phase III Trial after review of the data**
- **Lower, 800mg dose selected to use going forward**
- **800mg dose more conducive to fixed dose combinations**

**Melbourne, Australia, 4 June 2009: Avexa Limited (ASX: AVX)** announced that the Data Safety Monitoring Board (DSMB) met today to review the 16 week data from Avexa's apricitabine (ATC) Phase III clinical trial. The DSMB reviewed the data and recommended continuation of the study with the 800mg dose. Patients taking the 1200mg dose will be transitioned to the optimum 800mg dose to continue their therapy.

"We are delighted with the recommendation by the DSMB for the continuation of the Phase III trial," said Dr Julian Chick, Avexa's Chief Executive Officer. "The 800mg dose is considerably easier to formulate into fixed dose combinations, thus increasing the commercial potential for ATC. Given ATC's excellent safety and activity profile, these results allow us to move forward with increased confidence in ATC as a treatment option for HIV patients."

Avexa's Phase III trial compares ATC to 3TC in drug-resistant HIV patients. The 16 Week component had three arms comparing doses of ATC at 800mg and 1200mg to the 3TC control arm. A minimum of 50 patients were enrolled in each arm. In all three arms, patients received either ATC or 3TC as part of an optimized background regimen. The trial will continue with two arms comparing the 800mg ATC dose to 3TC. The Phase III trial is being conducted with more than 130 sites worldwide.

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. 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 U.S. Food and Drug Administration.

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### **About the Data Safety Monitoring Board (DSMB)**

The Data Safety Monitoring Board (DSMB) for Avexa is a group of international experts that reviews, on a regular basis, accumulating data from ATC's ongoing Phase 3 clinical trial. The DSMB advises Avexa regarding the continuing safety of trial subjects, as well as the continuing validity and scientific merit of the trial.

### **About Avexa**

Avexa Limited is a Melbourne-based biotechnology company with a focus on research and development 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. The Company's lead program, ATC, is an anti-HIV drug that has successfully completed the 96 week dosing of its Phase IIb trial and is currently in Phase III trials worldwide.

### **For more information:**

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