

**A V E X A**

Avexa Limited
ABN 53 108 150 750
576 Swan Street Richmond
Victoria Australia 3121

Telephone 61 3 9208 4300
Facsimile 61 3 9208 4004
Website www.avexa.com.au

Press Release

AVEXA REPORTS POSITIVE 96 WEEK DATA FOR HIV DRUG APRICITABINE (ATC)

- **No ATC resistance after 96 weeks**
- **Sustained efficacy over two years with strong safety profile**
- **No ATC-related Serious Adverse Events**
- **Week 16 Phase III study results due in second quarter of 2009**

Melbourne, Australia, 16 March 2009: Biotechnology company Avexa Limited ('Avexa') (ASX:AVX) today announced positive data from the ongoing Phase IIb clinical trial of apricitabine (ATC). After 96 weeks of treatment, no signature resistance to ATC has been identified. After 96 weeks of treatment, over 85% of patients continue to have HIV levels below detectable and all patients continue to receive ATC treatment. In addition, patients' CD4 cells (cells that are normally destroyed by HIV) continued to increase in number over the 96 weeks.

The key highlights of the data are:

- No resistance to ATC has been identified after 96 weeks of dosing
- CD4 cells in patients continue to rise with ongoing ATC treatment
- No ATC-related Serious Adverse Events
- No withdrawals from the trial due to side effects associated with ATC
- 39 patients completed the 96 week treatment period

"These data provide compelling evidence that ATC provides meaningful and sustained efficacy for at least two years, and in over 20 years of HIV drug development I cannot recall another drug where a signature resistance mutation is still absent after two years of dosing" said Dr Jonathan Coates, Chief Scientific Officer. "Many patients who have difficulties with their HIV treatment regime start to forget or avoid taking all the doses, which obviously affects the control of the disease. The fact that 95 percent of patients are correctly taking ATC after two years, without difficulty, is clear evidence that ATC can provide a safe, easy to take, effective and well tolerated addition to their therapy."

All of the patients who were originally assigned to the 3TC arm of the AVX-201 study, but who later switched to ATC, have now remained on ATC for more than 72 weeks without returning to 3TC. After two years of therapy on ATC, no serious adverse events have occurred and no patients have withdrawn from the trial because of any side effects related to the drug. Despite the availability of new classes of drugs for the treatment of HIV, 90% of patients on the study and their doctors are choosing to continue to use ATC rather than switch treatments. This provides a strong endorsement for ATC.

"We are pleased with the progress of ATC to date, not only in this Phase IIb trial, but also with our ongoing Phase III trial," added Dr Julian Chick, Chief Executive Officer. "2009 promises to be an exciting year for Avexa with our first data set from ATC's Phase III trial due in the second quarter. The clinical progression of the advanced programs, together with grant funded earlier stage assets has the Company well positioned to realise its potential."

**A V E X A**

Avexa Limited
ABN 53 108 150 750
576 Swan Street Richmond
Victoria Australia 3121

Telephone 61 3 9208 4300
Facsimile 61 3 9208 4004
Website www.avexa.com.au

Technical Details

The Phase IIb extension study is an open label trial for patients who completed the Phase IIb study. All patients continued to take 800mg ATC twice daily, with other HIV medications as required. Patients who entered the Phase IIb trial had already failed their HIV treatment, including 3TC, and some had failed multiple previous HIV treatments. In AVX-201, patients originally received either 600mg ATC, 800mg ATC, or 150mg 3TC, all twice daily. From week 24, all patients received 800mg ATC twice daily, and have now continued to 96 weeks of treatment in the Phase IIb extension study. The final endpoint of the Phase IIb extension study is at week 144.

At week 96, the number of patients whose plasma levels of HIV were below the limit of detection (<400 copies/mL) is approximately 87 percent. All patients continue to receive ATC. Levels of CD4 cells continued to increase, although more slowly which is expected as levels return to normal. At week 96, the average number of CD4 cells was around 500 to 600 cells/ μ L, very close to the levels of an uninfected, healthy individual. No evidence of resistance to ATC was observed up to 96 weeks of treatment.

Across the entire study, most adverse events were mild or moderate in nature. No serious adverse events related to ATC have occurred, and no patients have withdrawn from the study because of adverse events related to ATC.

About apricitabine (ATC)

ATC is currently in a Phase III clinical trial in HIV patients with NRTI resistance. 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 and Accelerated Approval distinctions with the U.S. Food and Drug Administration. More than 130 sites have been initiated for ATC's Phase III trial with initial 16 week data expected before the end of the second quarter of 2009.

About Avexa

Avexa Limited is a Melbourne-based biotechnology company with a focus on discovery, development and commercialisation 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 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. The company reported a cash balance of \$20.5M at the end of 2008.

www.avexa.com.au

For more information:

Dr Julian Chick
Chief Executive Officer
+61 3 9208 4300

Dr Jonathan Coates
Chief Scientific Officer
+ 61 3 9208 4300

Dr Susan Cox
SVP Development
+61 3 9208 4300