



## ASX Release

### AVEXA ANNOUNCES DETAILED ATC PHASE III RESULTS AT 24 WEEKS

**Melbourne, Australia, 23 March 2010: Avexa Limited (ASX:AVX)** announced today the detailed results from its apricitabine (ATC) Phase III study at 24 weeks. Although the study was stopped early, and therefore the results lack statistical significance, the detailed results show that HIV infected patients treated with 800mg of ATC twice daily experienced a positive clinical benefit versus the 3TC-based current standard of care. ATC was consistently active against all patient types from first-line failures to treatment-experienced patients and patients with high viral loads. The study results also show that in the more experienced patient population ATC achieved a 14% improvement over the standard of care with 3TC. Furthermore, a detailed genetic analysis of patients' virus isolates did not reveal any subgroups of HIV that would be likely to have a reduced response to ATC, which demonstrates that ATC should be active against the vast majority of HIV circulating in the infected population. ATC also continued to be extremely safe and well tolerated with no serious adverse events (SAEs) related to ATC.

"The detailed results at week 24 continue to produce evidence that ATC may provide clinical benefit to patients suffering from HIV, and who have limited options for therapy," said Dr. Julian Chick, Avexa's Chief Executive Officer.

As reported previously, the trial results showed that more patients reached undetectable viral loads on ATC versus the standard of care while the number of patients who lost control of their viral suppression (6.3%) was half that of those who received the best available standard of care (12.2%). In addition to reduction of viral loads, patients who received ATC experienced a greater recovery in their CD4<sup>+</sup> cell numbers, thus slowing progression of their disease. A decline in CD4<sup>+</sup> cell numbers is characteristic of progressive HIV disease.

Further key results at 24 weeks for the Phase III trial comparing ATC to 3TC in drug-resistant HIV patients:

- ATC was consistently active against all patient types from first line failures to experienced patients and patients with high viral loads. In patients with more than 100,000 copies per mL of virus in their blood 23% of these patients reached undetectable levels with ATC compared to less than 13% in the standard of care with 3TC arm.
- In more experienced patients with only two active drugs in their optimised background regimen (OBR) and whose virus contained the M184V mutation plus three or more TAMs, ATC achieved a 14% improvement compared to the standard of care with 3TC. The M184V mutation confers resistance to 3TC and FTC, and TAMs are mutations which confer resistance to AZT and a number of other NRTIs.
- In patients with a baseline CD4<sup>+</sup> cell count of less than 200 cells/ $\mu$ L, 14% more patients achieved <50 copies per microlitre when treated with ATC compared to those on 3TC.
- Overall ATC gave a more than 0.4 log<sub>10</sub> additional reduction in viral load compared to the standard of care alone when the effect of treatment on viral load was used.
- No sentinel mutations conferring resistance to ATC were observed during the 24 week treatment period. The few patients in whom genotypes could be obtained maintained their M184V mutation. Maintenance of the M184V mutation is believed to be beneficial to HIV patients as it reduces the ability of the virus to replicate.



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

Telephone 61 3 9208 4300  
Facsimile 61 3 9208 4146  
Website [www.avexa.com.au](http://www.avexa.com.au)

- ATC continued to be extremely safe and well tolerated. No SAEs related to ATC were observed in the trial, and less AEs were seen for ATC treated patients (26%) compared to those with the standard of care including 3TC (35%).
- In total 246 patients were enrolled into the study across the 3 arms (comparing 800mg ATC to 1200mg ATC and to 3TC, all with OBR). The 1200mg ATC dose was shown to have no benefit over the 800mg dose.

### **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 144 week dosing of its Phase IIb clinical trial. Phase III trials were commenced worldwide in January 2008 in HIV patients with NRTI resistance. Avexa's Phase III trial was conducted in more than 130 sites worldwide and compared ATC to 3TC in drug-resistant HIV patients who all received the current standard of care. The Phase III trial is a 48 week double blinded study in which patients were randomised to one of three arms; an 800mg ATC arm, a 1200mg ATC arm or a 3TC arm. After 16 weeks the 800mg dose was chosen as the preferred dose by an independent data safety monitoring board (DSMB) and the 1200mg dose arm was discontinued. In October 2009 Avexa announced that it would close the Phase III trial early to analyse the data after discussions with regulatory authorities. In previous clinical trials, ATC has shown the following characteristics: a unique resistance profile over 144 weeks of treatment, continued efficacy beyond two years of treatment, an excellent safety profile, and an ongoing immunological benefit.

### **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 for key projects including apricitabine (ATC), its HIV integrase program, its HCV polymerase program and an antibiotic program for antibiotic-resistant bacterial infections.

#### **For more information:**

Dr Julian Chick  
Chief Executive Officer  
+61 3 9208 4300

US: Investor Relations  
Remy Bernarda  
Blueprint Life Science Group  
[rbernarda@bplifescience.com](mailto:rbernarda@bplifescience.com)  
+ 1 415 375 3340 x2022

[www.avexa.com.au](http://www.avexa.com.au)