



ASX Release

Over 80% of patients on ATC achieve undetectable HIV after 24 weeks

4 September, 2007

Melbourne-based biotechnology company Avexa Limited (ASX:AVX) announced today positive 24 week data from the phase 2b clinical trial of apricitabine (ATC). The data demonstrate that, in over 80% of patients treated with ATC, the level of HIV in the blood was reduced to below detectable levels after 24 weeks. This was markedly better than those patients on the 3TC control.

“The level of response seen with ATC is remarkable for these patients, all of whom have already failed other drug regimens. The results indicate that with ATC, even drug-resistant patients with multiple previous treatment failures can achieve a response approaching that of previously untreated patients on first line therapy”, said Dr Julian Chick, CEO of Avexa.

Avexa also reported that in analysing CD4 cells of patients, there were CD4 cell increases of 28 – 39% and 73 – 86% in the ATC 600mg and 800mg arms respectively, compared to the 3TC treated patients. CD4 cells are essential for a healthy immune system, and it is these cells that are primarily destroyed by HIV infection. “This indicates that the potent suppression of HIV by ATC is benefiting the patients’ immune system, and is an important sign of the long term clinical benefit of treatment with ATC” said Dr Chick.

Avexa reported that no virus resistant to ATC has been identified after 24 weeks of therapy, which is consistent with the potent suppression of HIV replication and the ideal properties of a long-term anti-HIV therapy.

The safety profile of ATC continues to be excellent. No serious adverse events related to ATC have occurred to date and no patients have withdrawn from the trial because of any side effects related to ATC. Furthermore, 23 patients out of an eligible 24 have entered the ATC extension study. Two patients were ineligible for inclusion in the extension study. “The fact that such a high percentage of patients continue to enter the extension study tells us that these patients and their clinicians believe that ATC is providing meaningful therapeutic benefit in their treatment of the HIV disease” stated Dr Chick.

“These results clearly indicate that ATC regimens are potentially as effective, safe and durable as current first line regimens, but for drug-resistant patients that have already failed other drug regimens. This is excellent news for drug-resistant patients in need of potent, durable but safe new HIV therapies. These data will be submitted for presentation at a forthcoming international HIV conference ” said Dr Chick.

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
Head of Development
+61 3 9208 4300



www.avexa.com.au

Avexa Limited is a Melbourne-based biotechnology company with a focus on research and development of drugs for the treatment of infectious diseases. Avexa has dedicated resources and funding for key projects including its HIV integrase program and an antibiotic program for antibiotic-resistant bacterial infections. The Company's lead program is apricitabine (ATC), an anti-HIV drug which has successfully completed the 24 week dosing of its Phase 2b trial. Avexa continues to progress ATC towards Phase 3 trials. Avexa has entered into a collaboration with TargetDrug in China to identify new CCR5 inhibitors for the treatment of HIV infections and has an exclusive option to license TargetDrug's lead CCR5 inhibitor, nifeviroc.

Technical Details

AVX-201 is a 48 week trial with three segments. For the first 21 days, patients received 600mg or 800mg ATC twice daily, or continued on 3TC, without changing their background drug regimen. At day 21, patients continued on ATC or 3TC as before, but their background drugs were optimized depending on their treatment history and drug resistance. At week 24, all patients were offered open label ATC 800mg twice daily. Results from the initial 21 day period were reported by Avexa in March 2007. This announcement describes the data from the second segment of the trial to week 24.

At week 24, the number of patients whose plasma levels of HIV were below the limit of detection (400 copies/mL or 50 copies/mL, depending on the assay) was calculated. More than 80% of patients on either dose of ATC had plasma levels of HIV <400 copies/mL, and more than 70% of patients on either ATC dose had plasma levels of HIV <50 copies/mL.

Only four patients on ATC had sufficient levels of virus for genotyping at week 24, but none of them showed additional mutations in reverse transcriptase.

Remarkably, in ATC treated patients the level of CD4 cells in the patients' blood rose by more than 150 cells per milliliter on average. This marked increase demonstrates that ATC is able to not only halt the decline in CD4 cells seen in HIV infection but even reverse that decline, indicating that ATC is having a clinically beneficial effect on the patients' immune system.

Across the whole study, most adverse events were mild or moderate in nature, and mainly associated with gastro-intestinal disturbances. Six patients on ATC reported no adverse events at all up to week 24. No serious adverse events related to ATC have occurred to date, and no patients have withdrawn from the study because of adverse events related to ATC. Two patients were withdrawn from the study due to unplanned pregnancies.