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ASX Release

AVEXA ANNOUNCES ATC PHASE III TOP LINE RESULTS

Melbourne, Australia, 4 February 2010: Avexa Limited (ASX:AVX) announced today that the top line data from its apricitabine (ATC) Phase III study demonstrated a positive clinical benefit for ATC at 24 weeks versus the standard of care in HIV therapy. This data shows that while more patients reached undetectable viral loads on ATC, this was not statistically significant because the trial was stopped early and fewer patients were enrolled than originally projected. Avexa expects to present a more detailed analysis of the Phase III results by the end of the first quarter of 2010, and anticipates the data will continue to show a strong trend in favor of ATC.

Avexa's Phase III trial compared ATC to 3TC in drug-resistant HIV patients, dosing ATC at 800mg twice daily. At 24 weeks, ATC improved the overall clinical effectiveness of HIV therapy compared to the best available standard of care in four key aspects of clinical activity:

- the durability of viral load suppression to below detectable levels;
- the ability of ATC to improve immunological function by increasing the numbers of CD4+ cells;
- the effect of ATC on HIV disease progression; and
- ATC continues to be extremely safe and well tolerated, with no serious adverse events reported.

"These results highlight the ability of ATC to maintain suppression of patients' viral loads while increasing $CD4^+$ cell numbers, resulting in a clear clinical benefit to the patients," said Dr. Jonathan Coates, Chief Scientific Officer. "This data indicates that ATC could be a significant clinical addition to the drugs currently available including the new classes of HIV integrase and CCR5 inhibitors plus the new generation of NNRTis and protease inhibitors."

In the study, fifty-three percent of patients in the 800mg ATC arm had their viral loads reduced to undetectable levels. 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%). The percentage of patients below detectable in the standard of care control arm was 51 percent. The difference between the arms was in favour of ATC and compared well with the intended endpoint of 10 percent relative to the overall number of patients treated.

In addition to reduction of viral loads, patients who received ATC experienced a greater recovery in their $CD4^+$ cell numbers, thus slowing progression of their disease. A decline in $CD4^+$ cell numbers is characteristic of progressive HIV disease. Patients gained nearly 100 $CD4^+$ cells per microlitre compared to just over 70 $CD4^+$ cells per microlitre for those in the 3TC arm. The number of patients showing clinical progression of their disease was reduced when ATC was a component of their anti-HIV therapy compared to those who did not receive ATC (3.8% vs. 16.2%).

"The 24 week data from our Phase III trial has shown that ATC can improve clinical outcomes for patients suffering from HIV. This may position ATC as a complement to existing therapies in the HIV treatment landscape, including those recently approved," added Dr. Julian Chick, Chief Executive Officer.

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Summary Table

Parameter	800mg ATC Arm	Comparator Arm (3TC + current standard of care)	Comment
% patients suppressing viral load to <50 copies/mL	53	51	Positive trend in favour of ATC considering the number of patients
% patients who could not maintain control of their viral load suppression	6.3	12.2	More durable response for those patients on ATC plus the standard of care compared to the current standard of care alone
$CD4^+$ cell number increase (cells/microlitre)	98	73	Better immunological recovery for those patients on ATC
% patients with progression of their HIV disease over the 24 week treatment period	3.8	16.2	Improved clinical prognosis for patients who include ATC over and above the current standard of care

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. Phase III trials were commenced worldwide in January 2008 in HIV patients with NRTI resistance. Avexa's Phase III trial was conducted with 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 96 weeks of treatment, continued efficacy beyond two years of treatment, an excellent safety profile, and an ongoing immunological benefit. ATC targets a current unmet medical need that has earned the compound Fast Track status with the U.S. Food and Drug Administration.

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.

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