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ASX Release

AVEXA REPORTS POSITIVE PHASE IIb 144 WEEK DATA FOR HIV DRUG APRICITABINE (ATC)

- No ATC resistance and sustained efficacy after 144 weeks
- Strong safety profile with no ATC-related Serious Adverse Events

Melbourne, Australia, 15 February 2010: Avexa Limited (ASX:AVX) today announced positive data from the Phase IIb extension study for apricitabine (ATC). Of the 36 patients who successfully completed the full study, 94 percent maintained undetectable viral loads up to week 144. Importantly, in these patients, no resistance to ATC was detected and no ATC-related serious adverse events were observed. In addition, patients were able to maintain, on average, their CD4+ cells above 500 cells per microlitre, the level where many current guidelines indicate antiretroviral treatment need not be initiated.

“We are delighted that ATC continues to provide consistent, positive benefits for patients suffering from HIV,” said Dr. Jonathan Coates, Chief Scientific Officer. “These results, along with the initial data from the Phase III study announced earlier this month, provide a clear indication of the medical value of ATC.”

Thirty-six out of the forty-two patients that were enrolled into the Phase IIb extension study successfully completed the full study of 144 weeks, with ATC as part of their optimised background regimen (OBR). Thirty-four of those thirty-six patients maintained undetectable viral loads up to week 144. Of the patients who entered the study with a higher level of pre-existing drug resistance (more than two thymidine associated mutations, or TAMs), more than 90 percent of them achieved undetectable viral loads. This indicates that the activity of ATC is not compromised by increasing numbers of TAMs, a set of mutations that are known to mitigate the activity of other NRTIs such as tenofovir, abacavir and zidovudine.

Six patients did not complete the study, of which only two (4.7 percent) failed to maintain control of their viral load below detectable. Of these, one showed no additional mutations in the reverse transcriptase gene (the target of ATC and other nucleoside reverse transcriptase inhibitors, or NRTIs) and the other showed the presence of a mutation which is frequently related to the use of other antiviral agents in the OBR. Two patients were withdrawn from the study due to compliance issues and two for clinical trial eligibility reasons.

The excellent safety and tolerability profile of ATC has now been maintained beyond three years of treatment. Throughout the 144 weeks of study, no ATC-related serious adverse events were observed. Furthermore, there was no evidence of the associated side effects often seen with other anti-HIV drugs, which often necessitate a change in therapy. This is further confirmed by ATC’s high level of compliance, with more than 95 percent of patients taking their full dose of ATC consistently throughout the 144 week study.

About apricitabine (ATC)

Apricitabine (ATC) is an anti-HIV nucleoside reverse transcriptase inhibitor (NRTI). 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

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received the current standard of care. The Phase III trial was 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 after discussions with regulatory authorities. The top line data reported in February 2010 demonstrated a positive clinical benefit for ATC over the best available standard of care for HIV therapy. Improvements were seen for ATC in the control of viral replication, immunological recovery and disease progression while maintaining excellent safety and tolerability. These results are consistent with ATC's previous clinical studies, including the Phase IIb which has shown positive results out to 144 weeks. 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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