



ASX Release

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Avexa reports positive Phase IIb result ATC shows superior activity

Australian biotechnology company Avexa (ASX: AVX) today announced highly successful results from its Phase IIb trial for apricitabine (ATC). ATC is Avexa's novel nucleoside reverse transcriptase inhibitor (NRTI) being developed for the treatment of HIV infection in patients with drug-resistant HIV.

The Phase IIb trial compared the effectiveness of ATC in reducing the viral load of patients with drug-resistant HIV with the effectiveness of lamivudine (3TC), a leading NRTI in widespread use. A total of 47 patients completed 21 day dosing. Of these 17 patients received 600 mg doses of ATC, 16 received 800 mg doses of ATC and the control group of 14 patients were treated with 3TC.

The results for patients in both ATC cohorts exceeded the Phase IIb trial primary endpoint by a substantial margin. Patients who received ATC achieved on average a reduction of greater than $0.8 \log_{10}$ (85%) in the level of HIV in the blood after 21 days treatment compared to a reduction of less than $0.03 \log_{10}$ in patients treated with 3TC. Nine patients achieved a greater than $1.5 \log_{10}$ (97%) reduction after 21 days, with 3 patients achieving a reduction of over $2.0 \log_{10}$ (99%). Remarkably, one patient achieved a decrease in the amount of virus of more than $2.5 \log_{10}$ (99.7%) after 21 days on ATC. Patients with the highest degree of drug resistance still achieved a significant benefit from treatment with ATC. The demonstration of superior activity in this study indicates that ATC will be an effective antiviral drug for the treatment of many drug-resistant patients, including even those most highly resistant.

"This is a fantastic result for Avexa" stated CEO Dr Julian Chick. "The positive result allows us to continue to progress ATC into Phase III trials and towards commercialisation. The team at Avexa has done a great job and these excellent results show that their hard work has paid off."

During the study there were no Serious Adverse Events (SAEs) related to the study drug, and no patients withdrew from the study because of side effects of study drug treatment. ATC continues to be very well tolerated, with some patients having received more than 12 months treatment to date. Currently there are 14 patients in the open label section of the Phase IIb trial and 6 patients have elected to enter into an extension study (where they continue to be treated with ATC), having completed the full 48 weeks of the study.

"These outstanding results clearly position ATC to become the most effective and well tolerated NRTI for treatment of drug-resistant HIV" stated Dr Jonathan Coates, Avexa's CSO, and co-inventor of 3TC, a NRTI marketed by GSK.



The emergence of resistance to antiviral drugs is one of the most important reasons for treatment failure. No evidence of mutation in the virus resulting in resistance to ATC was detected over the course of the 21 day treatment. This indicates that antiviral resistance to ATC does not occur quickly and gives ATC a significant competitive advantage over several other drugs which can rapidly select for resistance.

“Overall the results of Avexa’s Phase IIb clinical trial demonstrate that ATC is a clinically effective antiviral drug that can significantly reduce the replication of the virus in patients infected with drug-resistant HIV” said CEO Dr Julian Chick. “Moreover, these results demonstrate that ATC is a safe drug not associated with undesirable side effects. In addition, there was no evidence of ATC resistant virus emerging over the trial period. All these results indicate that ATC has the properties required to position it as the NRTI of choice for the treatment of patients failing their first line or subsequent anti-HIV drug regimens.”

Global HIV market

It is estimated that over 40 million people are currently infected with HIV, with over 1 million of these children. It is currently estimated that around 1.4 million people in North America and around 2.2 million people in Europe have HIV.

Once on therapy, patients with HIV will typically take a minimum of 3 drugs daily in combination. This may increase as a patient progresses into 2nd and 3rd line therapy or into salvage therapy, when patients have developed what is commonly referred to as AIDS. Second line patients are defined as patients who show resistance to at least one class of HIV drugs, while 3rd line and salvage patients typically have resistance to multiple drugs and drug classes. Avexa is aiming to position ATC as the NRTI of choice for the treatment for patients in 2nd and 3rd line therapy and salvage therapy, as well as for the growing number of treatment naïve patients presenting with HIV virus resistant to the current front line therapies. In 2005 HIV drugs generated sales globally of USD \$6.6 billion, with NRTIs representing greater than 50% of the overall market.

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Avexa Limited is a Melbourne-based biotechnology company with a focus on research and development of drugs for the treatment of infectious diseases, in particular diseases which have a significant unmet medical need. Avexa has dedicated resources and funding for key projects including antiviral drugs for HIV and an antibiotic alternative for antibiotic-resistant bacterial infections. The Company’s lead program is apricitabine (ATC) which has recently successfully completed the 21 day dosing of its Phase IIb trial. The Company continues to progress ATC towards Phase III trials.



Technical Data

Trial Design

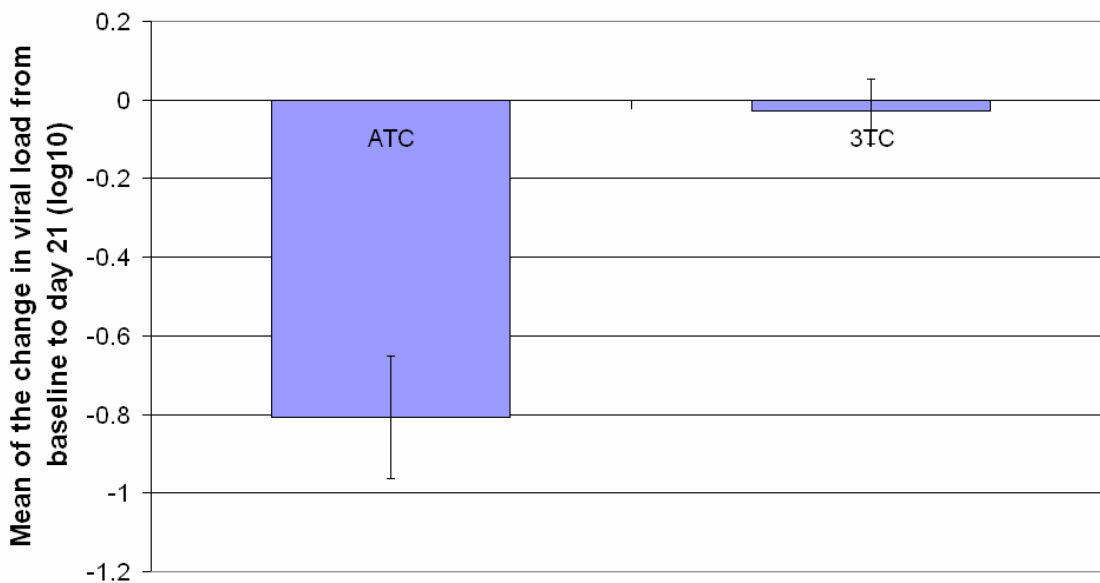
AVX-201 is a randomised, double blind study of two doses of ATC compared to lamivudine (3TC) in treatment-experienced HIV-1 infected patients with the M184V mutation. Patients were randomised to receive 600mg or 800mg ATC twice daily, or 3TC twice daily, for 21 days, in a blinded fashion. The primary endpoint of the study is the change in the amount of virus in the blood (viral load) after 21 days treatment.

After day 21, patients continue to receive either ATC or 3TC up to week 24, but can also change their other background HIV medicines. After week 24, all patients openly receive ATC unblinded to week 48. After week 48, patients may elect to enter an extension study (AVX-201E) in which they continue to receive ATC in addition to their other HIV medicines.

47 patients were analysed after 21 days of treatment. Approximately one third were female, and approximately half had the highest levels of drug resistance. The majority of the patients were recruited in Argentina, with patient ages ranging from 22 to 59.

Efficacy data

Reduction in viral load in patients treated with ATC or 3TC



Bars on the figure above indicate the standard error of the two groups.

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Safety data

No ATC drug-related serious adverse events have been observed to date. No patients have been withdrawn from the trial because of side effects related to ATC treatment. In particular there has been no significant incidence of hyperlipasaemia (an indicator of pancreatitis) or elevated liver enzymes (suggestive of liver toxicity) related to ATC. These are two serious and undesired side-effects associated with some other NRTIs. These data demonstrate the good safety profile for ATC in the clinical setting.

Full scientific data from the Phase IIb trial will be presented at an upcoming international scientific conference.