



ASX Release

Avexa and European Medicines Agency agree path forward for ATC

Melbourne, Australia, Wednesday 21 March, 2012: Australian biotechnology company Avexa Limited [ASX:AVX] Avexa today announced that following two recent meetings with the European Medicines Agency (EMA), it has now received positive responses regarding the Phase III clinical development of apricitabine (ATC), the company's key anti-HIV drug. The EMA's response is very similar to that received by the company after meeting with the US Food and Drug Administration (FDA).

The EMA is a key regulatory body which governs approval of new drugs in almost all European countries. Avexa approached the EMA following the successful discussions with the FDA, and the company was recently invited to attend a working party to further discuss ATC's Phase III clinical development.

Avexa is pleased to announce that it has now received a response regarding the regulatory requirements for approval of ATC in Europe that is very consistent with that of the FDA.

"This means that an expedited pathway for approval of ATC has now been clarified with both the FDA and EMA, which together regulate the approval of drugs in the world's two largest pharmaceutical markets," said Dr Jonathan Coates, Avexa's CSO and interim CEO. "Importantly, regulatory authorities in many other countries typically follow the requirements of one or both of these two key authorities."

As previously announced, ATC is now well positioned for an expedited and less costly path to approval in the world's two largest HIV drug markets. Together with the recent new patents filed (see announcement released by AVX on 23rd November 2011), ATC's Phase III clinical development and eventual commercial value have become significantly clearer.

Mr Iain Kirkwood, Avexa's Chairman, said: "We are very pleased to receive this positive response from a second major regulatory body which corroborates ATC's great potential as a safe and effective new treatment for people with HIV. Avexa continues to improve ATC's commercial potential, underlined by the two patent applications filed late last year. Also we continue to evaluate and implement the best strategy to get ATC to market. This is a key objective as we remain convinced that the potential sales for ATC are likely to be substantial."

About Avexa Limited

Avexa Limited is a Melbourne-based biotechnology company with a focus on discovery, development and commercialisation of small molecules for the treatment of infectious diseases. Avexa's key projects include apricitabine (ATC) for the treatment of drug-resistant HIV, an HIV integrase program and an antibiotic program for antibiotic-resistant bacterial infections.

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