



## ASX Release

### Avexa and FDA agree path forward for ATC

**Melbourne, Australia, Monday 28th March, 2011:** Australian biotechnology company Avexa Limited [ASX:AVX] today announced that it has successfully completed a comprehensive and highly productive meeting with the US Food and Drug Administration (FDA) in which the remaining regulatory pathway to final approval for the company's key anti-HIV drug Apricitabine (ATC) has been agreed.

Most importantly, the FDA has recognised and given credit for the significant amount of previous ATC clinical studies conducted by Avexa, in particular the latest ATC study AVX-301. As a consequence, the remaining regulatory requirements for an ATC approval are considerably less complicated and less extensive than previously assumed and less than that required for other recently approved drugs.

In summary Avexa can now expect:-

- Clearer, simpler, and faster regulatory path forward to approval
- Considerable "risk of failure" mitigation
- Significantly less cost resulting in better economics for ATC
- An immediate Phase III with near term approval potential
- ATC to be far more attractive economically to potential partners

Initially ATC will be developed for HIV patients who have developed resistance to multi-drug therapy. ATC has shown great potential as a therapy in the fight against multi-drug resistant HIV. As a twice-a-day dosed drug, ATC, with its recognised excellent safety profile, complements the new generation of anti-HIV drugs such as Isentress<sup>®</sup>, Merck's HIV integrase inhibitor, which are also dosed twice daily. As a novel nucleoside, a class which is well known to be a vital component of anti-HIV therapy, ATC offers a new extension to existing therapies in the treatment of HIV especially for those patients with limited remaining therapeutic options.

"The meeting with the FDA has provided a clear and expeditious regulatory pathway for ATC. This is a significant milestone for Avexa and its shareholders" said Dr Jonathan Coates, Interim CEO "we can now plan the next regulatory steps for the programme with confidence and secure the commercialisation of this very valuable anti-HIV drug"

#### 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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