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## **Company announcement**

## Avexa makes progress on North Pratt Coal Mine in Alabama Revenues to fund development of HIV drug ATC expected in late 2013

Monday 22 April 2013

**Melbourne, Australia** Australian biotechnology company Avexa Limited [ASX:AVX] today announced that a draft permit to commence mining activities at its North Pratt Coal Mine in Alabama, USA, has been issued to North Pratt for public comment by the Alabama Department of Environmental Management. In November last year Avexa announced it would invest US\$4 million (A\$3.88 million) to purchase a 25.5% equity share in Coal Holdings USA LLC (Coal Holdings) – which owns the mine operating company North Pratt – with the aim of generating cash flow to fund Avexa's key drug candidates.

Avexa understands from Coal Holdings that the Environmental Protection Agency (EPA) will also review the draft permit during this period and in the absence of any major objections, the permit would be fully approved after the statutory 30-day waiting period. Granting of the final permit, which is anticipated to take place by early June, will allow mining operations to commence.

In the absence of any unforeseen contingencies Avexa expects the mine to begin to generate revenues by late 2013.

The North Pratt Coal Mine is situated about 15 kilometres north of Birmingham, Alabama. In November last year Avexa announced it would invest US\$4 million (A\$3.88 million) to purchase a 25.5% equity share in Coal Holdings USA LLC – which owns the mine – with the aim of generating cash flow to fund Avexa's key drug candidates.

Mr Iain Kirkwood, Chairman of Avexa, said it was pleasing to see the company's novel strategy for funding ATC and Avexa's other projects proceeding according to plan.

"We are pleased that we are now close to receiving the final approvals which will enable mining activities to begin. Revenue is likely to be generated later this calendar year. These revenues will be used to fund the final clinical development of apricitabine (ATC), our late stage drug candidate for drug- resistant-HIV, prior to seeking marketing approval. This strategy was outlined to our shareholders at the company's Annual General Meeting in December."

He added, "I am delighted with the progress that has been made towards achieving our primary goal of getting ATC approved for sale. At the same time we have put in place potential marketing partners who are keen to sell this valuable drug in the fight against HIV/AIDS."

In parallel with establishing marketing partners, Avexa has been continuing to undertake the many preparatory activities that are required prior to the formal initiation of the AVX-305 Phase III clinical trial. These include the development of clinical trial protocols, identification and ratification of



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clinical trial sites around the world, preparation of clinical trial materials and drug stocks, and the required ongoing regulatory activities.

The remaining clinical development of ATC centres on a 300-patient clinical trial with a 14-day primary end-point of reduction in viral load (AVX-305). A previous clinical trial for ATC (AVX-201) also used the same primary endpoint, but at a time point of 21 days, and the results were both clinically and statistically significant. Avexa is confident that ATC will meet the required endpoint for approval. Indeed, in its last clinical study (AVX-301) ATC showed an impressive clinically meaningful reduction in viral load even out to 24 weeks, over and above that of the background regimen, even though that study was concluded prior to full recruitment.

The AVX-305 study will begin as soon as the Avexa Board is confident of sufficient underpinning cash flows from the coal mine investment or other equivalent financing. The company will continue to pursue its other projects, particularly its promising anti-HIV integrase inhibitors and antibiotic program with Valevia GmbH.

For more information:

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**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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