

Biotech Daily's CEO interview

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AVEXA, A BIOTECH PARADIGM - DR JULIAN CHICK

IN WHAT MAY BE a paradigm case for an emerging biotechnology company, Avexa sounds like it is on the cusp of greatness.

The company's lead drug, apricitabine for HIV, appears to work and phase III is tantalizingly close, albeit expensive.

Recruitment delays pushing back Avexa's phase IIb HIV trial 12 months have cost the company "less the \$1 million" according to chief executive officer Dr Julian Chick.

Following an ABN Amro Morgans breakfast presentation for investors and specialist media, Dr Chick told Biotech Daily that the delay was hard to quantify because staff were diverted to other tasks, but agreed that it "could cost 10 to 15 percent" of the \$6-8 million budget for the phase IIb trial.

In February this year Avexa said it expected to have results from the trial "in the first half of 2006" but competing trials, some at phase III level and run by large pharmaceutical companies have meant slow recruitment in Australia for the trial of AVX754 or apricitabine.

The problem has been solved by running trials in Argentina with the total recruitment of 45 to 50 patients now expected "by the end of the year".

Avexa's chief scientific officer Dr Jonathan Coates, co-discovered the anti-HIV drug 3TC (lamivudine) with Biochem Pharma in a venture with Glaxo and later Glaxo Wellcome. Biochem Pharma was then bought by Shire Pharmaceuticals and Avexa has licenced ATC (apricitabine) from Shire.

ATC is described as "the next generation" of nucleoside reverse transcriptase inhibitors (NRTi). Avexa's target market is for HIV patients who have become resistant to the first line treatment by 3TC.

Dr Chick said that 65 percent of HIV patients are in the second line of treatment, with resistance to 3TC found in the M184v mutation in reverse transcriptase gene, the target of 3TC one of the components of first line treatment. Dr Chick says his company's apricitabine is "the drug of choice after first line failure".

"It is the NRTi for NRTi resistance," said Dr Chick.

Of the patients so far recruited for the minimum 48 week trial, two patients have gone on to an extension study beyond the 48 weeks and five to 10 patients are in the "open label" stage of the trial having been on the drug for 24 weeks.

The endpoint for the first three weeks of blind trial is a "0.6 log decrease" in virus levels in blood, which is a statistically significant decrease demonstrating clinical utility.

The company is also undertaking two parallel phase I trials: a cardiac safety study and a co-dosing phase I trial with tipranavir, along with continuing its work on compounds targeting HIV integrase and antibacterial compounds.

Dr Chick says the next step for Avexa is preparation for the phase III campaign. Both he and Dr Coates said that once the phase III trial was underway the chances of success to registration increased dramatically. They said that "not a single drug that has started phase III trials has failed phase III trials".

Dr Chick hoped the two-year phase III trial would be completed in 2009 with a filing to the US Food and Drug Administration at the end of 2009 and in the market by 2010.

The cost of the trial is expected to be \$50 million and although the cash on hand is \$20 million, Dr Chick agreed there would need to be significant capital raising.

He said that two large US funds had bought into the company with Passport Management a substantial shareholder and he would be looking to investors to make up the funds or perhaps consider partnering with a large company.

Sales of 3TC were more than \$US1.0 billion a year.

[Avexa was unchanged at 22 cents.](#)