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Marc Sinatra's Bioguide Brief:

Avexa's ATC Harder To Kill Than A Cockroach

The only people who seemed to believe that Avexa's HIV drug apricitabine (ATC) wasn't dead, were a few at Avexa's headquarters.

A major complaint of Avexa's current management has been that the former management did not engage with the US Food and Drug Administration as much as they should.

According to Avexa's announcement today, they were right.

Faster to market, less risk, less cost, better returns, an immediate phase III trial (funny, I thought they had already been in a phase III trial) and, of course, ATC will be more economically attractive to potential partners.

Now a few HIV market facts:

- * Intelence was the last HIV drug approved – three years ago;
- * Of the seven drugs for HIV in late stage testing three years ago, none have made it to market;
- * Combination pills rule the HIV landscape – and new ones appear to be on the way;
- * New delivery methods mean even less than once-a-day dosing is likely;
- * The efficacy of existing therapies makes it very difficult to show a benefit with a new drug; and
- * Doctors want years of performance before they put a patient on a new drug.

The upshot of all of this is that current treatments for HIV are very good and that the disease is now a chronic one, not a death sentence.

So, is there a possible role for ATC in HIV treatment? The answer to that question seems to be possibly, but not likely.

HIV is very adept at mutating and eventually we are likely to see a new strain for which current therapies seriously lack efficacy.

ATC may well be able to treat these new strains, but it is likely that a whole bunch of other HIV drugs that have failed to get to market will be able to do so as well.

And then there is the elephant in the room, ATC's patent life.

Should everything go exceptionally well, ATC may get on the market just as its patent expires in 2013. Yes, there will probably be extensions and data exclusivity for new chemical entities, but we are talking bare bones protection.

Avexa says they have manufacturing patents which provide cover until the "mid-20s", a strategy that has worked for Chemgenex, but verifying these claims is exceedingly difficult.

For Avexa's sake and Australian biotechnology's sake, let's hope Avexa can get ATC to market and that significant cash flows result.

I might not hold my breath, though.

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