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EP Vantage interview – Antisense aims to ride Kynamro's slipstream to market

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The approval in the US of Isis Pharmaceuticals' Kynamro has finally validated antisense technology as a therapeutic approach. And for Isis's long-term collaborator Antisense Therapeutics, the approval is more than just an affirmation of the technology's potential: it provides concrete advantages in the shape of a clinical development pathway and a precedent that could help it hook investors and partners.

"It's a very significant event," Mark Diamond, Antisense's chief executive, tells *EP Vantage* in an interview. "There has been some scepticism about whether this would ever happen, so it's nice to see that removed now. We think it's going to advantage us with investor interest and partnering interest."

Satellite

Antisense is a sort of satellite company to Isis, Mr Diamond says, and the two go back a long way to when Antisense listed in Australia 12 years ago. "All the drugs in our pipeline are antisense drugs that we've got from Isis," Mr Diamond says. "Kynamro has the same chemistry as the technology we're commercialising."

The relationship is a close one, he explains: "We advise Isis what drug targets we want to work on. Then they hand us over a lead inhibitor, and we get worldwide exclusive licences to those drugs for all therapeutic applications. We take it from there, into preclinical studies and clinical development. That's the course that we took with these drugs we're developing now."

The arrangement allows Isis to seed its technology widely; the California group got a foothold in Australia thanks to Antisense. "When we listed, Isis got ownership in the company and ... as we successfully commercialise [the candidates] they get a share of the commercial proceeds," says Mr Diamond.

Big year

The coming year is a crucial one for Antisense. With one drug, a multiple scelrosis candidate, having just completed phase II trials, and another, for acromegaly, having just entered a three-month phase II study, if all goes to plan 2013 could see the firm touting two viable candidates and in a position to seek partnerships.

The company's MS drug, ATL1102, targets the VLA-4 receptor, Mr Diamond says. "This has quite a high profile in the MS world because it's the same biological target as Biogen Idec's Tysabri. We've shown that drug works in phase II clinical trials in MS patients, so we're about to complete a chronic toxicology study in that drug which will potentially take us into phase IIb."

ATL1102 is partnered in China with Tianjin International Joint Academy of Biotechnology and Medicine, which will fund the toxicology study. It is also in development as an inhaled formulation for asthma.

The acromegaly candidate, ATL1103, might leapfrog the further advanced ATL1102 to become Antisense's first marketed product. "It's an orphan indication, acromegaly, so we'd benefit from the more streamlined clinical development path," Mr Diamond says. "That's probably going to be on the market before the MS drug, because the next phase of development for the MS drug would be phase IIb ... and phase III clinical trials in MS usually take a couple of years to do."

He explains that obtaining approval for an acromegaly drug is relatively straightforward. "The goal with treating acromegaly is to normalise IGF-1. That's also the way in which these drugs are approved: in regulatory trials all you have to do is show that you're normalising IGF-1." Consequently, Antisense expects to be able to seek approval of ATL1103 based on phase III trials, which would begin following the three-month phase II study and last around a year or 18 months. "It's going to be quicker development," Mr Diamond says.

Partnering

The company raised Aus$6.5m last March and is funded through to next year, Mr Diamond says, allowing completion of the forthcoming phase II trial of ATL1103. After that, it looks like it may follow the oft-travelled route of seeking partners.

In fact, Mr Diamond says, Antisense almost had a partner for its acromegaly candidate before phase II, but the potential licensee walked away. “The company went through full licensing due diligence with us.” However, it was subsequently decided that the discussions would be put on hold until the completion of the phase II clinical trial.

Negotiations with the undisclosed suitor could pick up where they left off, Mr Diamond said, if the phase II data are strong. “We expect them to be there and be interested in the data – we hope they will be – but we’re not expecting them to be the only prospect for licensing this drug.”

Partnership is not the only possibility for ATL1103, though. “Probably the more likely path would be to partner it at the end of the phase II clinical trial, but we’re aware that as this is an orphan drug indication the requirements for a phase III study are reduced. To be able to fund (development of) a product ourselves is not out of the question.

“At the completion of the phase II clinical trial we’d be looking to find partners, but what it also might present is an opportunity for us to raise money and go and complete phase III studies ourselves,” Mr Diamond says, as well as speculating that decent data would make Antisense a takeover target. “That’s something that we will contemplate,” he says.

While Kynamro is in itself unlikely to set the world on fire, its potential as a harbinger will doubtless cause increased interest in antisense compounds (*Isis needs to follow Kynamro with bigger and better pipeline wins, January 30, 2013*). But one is not enough. At the end of this year the value of Antisense, Isis Pharmaceuticals and the underlying technology itself will have become clearer.

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