

Medivation miscue allows Aragon to fall to J&J



Jacob Plieth

If it did not before, Medivation must surely now be rueing the day it allowed its lawsuit against Aragon Pharmaceuticals, the private US biotech bought yesterday by Johnson & Johnson, to reach the courts.

Aragon's win in that case in December set the wheels of the J&J deal in motion, and now Medivation faces a new – albeit early-stage – threat to its potential prostate cancer blockbuster Xtandi. Given how strong a case Aragon had, Medivation should simply have eliminated it with a swift takeover long before the bidding ever reached the \$650m handed over by J&J yesterday.

After all, Medivation had had Aragon just where it wanted it – hamstrung by litigation in efforts to develop ARN-509, an anti-androgen closely related to Xtandi, while Medivation proceeded swiftly with its own drug. Xtandi was approved for castration-resistant prostate cancer last August.

Xtandi and ARN-509 had been discovered at the same UCLA laboratory, and Medivation had sued Aragon, claiming rights over a series of compounds including ARN-509. Although a settlement involving a royalty or a simple takeout by Medivation seemed the easiest solution the case went to the Superior Court of California, whose verdict was unequivocal: Aragon owned exclusive rights to the compounds ([Asco-GU gives prostate cancer's dark horses starring roles](#), February 5, 2013).

Shortly afterwards Aragon presented data at Asco-GU, showing that in a phase I/II study ARN-509 led to a 50% or greater PSA decline in 91% of men with early-stage castration-resistant prostate cancer. A takeover was thus inevitable, but by this stage Aragon had likely become too expensive for Medivation.

Impressive price

Indeed, the price that Aragon has attracted is impressive given the early stage of its pipeline. The \$650m up front will be followed by up to \$350m if certain undisclosed milestones are met.

Medivation fell 7% yesterday on news that the buyer was its prostate cancer rival J&J. Aragon thus becomes the latest private biotech to be snapped up by big pharma.

Only ARN-509 and related androgen receptor antagonist assets are included in the deal, and all of Aragon's other work, including the phase I selective oestrogen degrader ARN-810, will be spun out into a new company, Seragon Pharmaceuticals, in which J&J will have no interest.

For J&J the purchase makes perfect sense given the direct competitor to its Zytiga that Xtandi had become in the fast-developing prostate cancer space. In ARN-509 J&J obviously found an opportunity to go one up on Medivation, both in terms of what might be a better drug and as a possible strategy to extend its franchise beyond the 2017 expiry of key Zytiga patents.

If ARN-509 is anywhere near as efficacious as Xtandi it might, for instance, not have to be given with steroids, which many urologists prefer to avoid owing to their side effects. While Zytiga does have to be given on top of steroids Xtandi has been shown to improve overall survival independent of steroid use.

Superiority

Still, much remains to be proved. The Asco-GU data related to the first published human study of ARN-509, and the project is in one phase II trial in just 90 patients. Moreover, mere superiority over placebo will unlikely cut much ice, and ARN-509 will have to prove itself better than the likes of Xtandi and other recent market entrants.

So given that ARN-509 remains very much a longer-term threat to Xtandi, the Medivation share price wobble might be an overreaction. Medivation is also continuing to pursue the case against Aragon, on April 15 filing an appeal against the earlier summary judgment, as well as separately suing Dr Michael Jung, one of the ARN-509 co-inventors, for fraud.

But J&J must have carried out extensive due diligence into the matter and concluded that the IP is sound. As such the best that the litigation achieved was to cause Aragon to lose valuable time – despite which it

nevertheless raised \$42m in one of the more impressive venture capital rounds of last year.

Medivation, and its Xtandi partner Astellas, should really have acted more quickly when the asset was still cheap.

Study	Detail	Trial ID
21-pt ascending-dose phase I	Completion 2014	NCT01792687
123-pt open-label phase I/II	Presented at Asco-GU	NCT01171898
90-pt phase II	Completion 2015	NCT01790126

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