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Allergan’s pipeline takes its turn in the spotlight

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It is rote by now: acquisition quarry goes on public relations offensive to demonstrate the value to shareholders of remaining independent. Valeant’s prey Allergan arguably has the most tangible evidence to support this ploy of any of the recent takeout targets.

The California-based group took the opportunity of an expanded FDA approval for its eye implant Ozurdex yesterday as a springboard to tout its pipeline, particularly its potential Lucentis competitor abicipar pegol. The positive phase II data Allergan revealed should strengthen its case that the earnouts that Valeant has offered as part of its bid do not properly recognise the value of this asset.

Another delay

In terms of helping its market value, Allergan’s announcements did little: shares fell 3% to $169.22, as the most immediate news was an FDA rejection to the inhaled migraine treatment Semprana, formerly known as Levadex. This was the project's second rejection, the first coming before Allergan bought MAP Pharmaceuticals; as with the first complete response letter, the issue was manufacturing, not safety or efficacy (*Allergan hopes Map buyout does not bring more headaches, January 23, 2013*).

Investor disappointment was understandable, although maybe overdone since the company estimated that the knockback should delay launch by only up to a year. That agent, a reformulation of dihydroergotamine mesylate, was expected to sell $29m this year, rising to $405m in 2020, according to *EvaluatePharma*’s consensus, making it the company’s third-biggest growth driver.

Beyond that, there was nothing but good news from Allergan. Ozurdex, a corticosteroid-secreting intravitrial implant, saw its FDA label expanded to include diabetic macular oedema in patients with artificial lenses or awaiting cataract surgery, in addition to the approved indications of macular oedema and uveitis.

Allergan also said it had decided, after a meeting with the FDA, to advance a bimatoprost sustained-release implant into phase III trials in glaucoma and elevated intraocular pressure. The decision was based on mid-stage data in which the implant equalled daily eye drops of the topical form of the prostaglandin F2 analogue Lumigan.

Seeing opportunity

The big prize, however, is the promise of advancing abicipar pegol, also known as AGN 150998, into a head-to-head phase III trial against Lucentis in wet age-related macular degeneration (AMD) early next year. That agent is part of an ongoing relationship with the private Swiss biotech Molecular Partners on its platform of small proteins called DARPins.

The decision was based on phase II data in which injections of abicipar pegol at baseline, four weeks and eight weeks improved visual acuity at 20 weeks as well as Lucentis injections at baseline, four, eight, 12 and 16 weeks.

The phase III plan is to compare two doses of abicipar pegol, one every eight weeks and one every 12 weeks, against Lucentis injections every four weeks. The goal is to reduce the number of injections for AMD patients, as Regeneron Pharmaceuticals’ Eylea has sought to do. The DARPin collaboration includes a second AMD agent, AGN-151200.

This news was sufficient for UBS analyst Marc Goodman to add $425m to his 2020 sales forecast for abicipar, bringing the total to $950m. In total, Mr Goodman said the news announced yesterday resulted in a $810m increase in his sales forecasts for Allergan, which he said should change investors’ views of the company.

“We would expect shareholders to incrementally appreciate the company’s stand-alone prospects and think twice about the benefits of the Valeant deal,” Mr Goodman wrote. “Investors may be tired of hearing about the DARPin, but the reality is that this product has an excellent chance of being a material new franchise.”

Leerink analyst Seamus Fernandez, however, noted that Lucentis underperformed in the phase II trial; in addition, abicipar caused several cases of ocular inflammation. Taken together, the data Allergan released “are

unlikely to eliminate questions around DARPin's long-term commercial viability", Mr Fernandez wrote.

This has been a key sticking point to Valeant's bid, as it has offered contingent value rights to Allergan's shareholders of up to $25 a share along with committing $400m to develop the DARPins. Many have questioned this manoeuvre, pointing out that Valeant is not known for its drug development (*Valeant is unlikely to have long term vision for Allergan's eye assets, May 29, 2014*).

Allergan has increased the value of this asset by putting it into phase III, but questions over its potential will remain. Shareholders might be more convinced if Valeant pledged a spinout of that franchise in a way that would give them the promise of immediate returns and a future income stream.

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