Evaluate Vantage

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For AbbVie filgotinib becomes no-go-tinib

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Galapagos's filgotinib had until now been seen as a highly promising rheumatoid arthritis project, so AbbVie's surprise decision not to opt into its development is a quadruple whammy for the Belgian biotech.

The most sinister read of today's decision is that AbbVie had seen something negative in the compound's phase IIb results, but until the full data are published investors will not know for sure. In the near term Galapagos now faces a large competitor, and its stock will also be hit as the market removes first the $200m AbbVie would have paid to opt in, and then the premium on an assumed subsequent takeover.

It was a measure of filgotinib's promise that positive phase IIb result toplined in April caused Galapagos's stock to more than double over the next five months (*Galapagos moves towards RA deal but a dark horse remains on the horizon, April 15, 2015*). The shares initially crashed 30% this morning, before recovering some of the losses.

Safety data

There could be further panic ahead until more detailed safety data from the filgotinib trial are released. Mark Schoenebaum, an analyst with Evercore ISI, said safety was the key to widespread physician adoption of the Jak inhibitor class.

AbbVie's decision was based on a review of filgotinib alongside its own internal candidate, ABT-494. At the same time as revealing that it was handing back to Galapagos the filgotinib option AbbVie revealed efficacy data from two hotly awaited ABT-494 phase II trials.

At first glance there seems little to distinguish between the two compounds in efficacy terms, and they both seem better than Pfizer's Xeljanz at its approved dose, and on a par with the high dose of Lilly's baricitinib, though these are of course across-trial comparisons.

12-week efficacy of selected Jak inhibitors

Agent/dose	ACR20*	ACR50*	ACR70*
ABT-494 24mg once daily	32%	24%	18%
Filgotinib 100mg twice daily	35%	40%	23%
Filgotinib 200mg four times daily	24%	28%	16%
Baricitinib 2mg four times daily	13%	7%	6%
Baricitinib 4mg four times daily	34%	25%	21%
Xeljanz 5mg twice daily	28%	21%	8%

*Source: Evercore ISI; *placebo-adjusted.*

However, AbbVie released nothing about ABT-494's safety beyond stating that its overall profile was favourable. And, while detailed filgotinib data have not been published, they will have been shown to AbbVie as the group deliberated whether to opt in.

All that said, it might be too early to assume the worst for Galapagos. The Belgian biotech had earlier commented that it would have been happy to waive an opt-in obligation that had existed in certain circumstances, suggesting that it thought finding a new partner would be simple.

But AbbVie putting all its effort behind ABT-494, which it now claims has best-in-class potential, puts the pressure on Galapagos not only to find a new partner but to find one with sufficient sales firepower to compete

against AbbVie; Johnson & Johnson would do nicely. It is also disappointing for Galapagos that AbbVie rejected the possibility of licensing in filgotinib while repositioning ABT-494 for oncology indications.

The most benign possibility is that the US big pharma group took a purely economic decision, and that there are no safety scares lurking in the background. It could simply have looked at the numbers and decided that it made no sense to pay a fee, milestones and royalties when it could just switch to a near-identical unencumbered in-house project.

This will be the hope to which Galapagos bulls will cling as their company moves to find a new licensee.

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