Evaluate Vantage

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Galapagos' punishment for loss of RA lead looks harsh

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Galapagos saw a quarter of its market value erased today - €77m ($111m) - on news that its phase II rheumatoid arthritis candidate, GLPG0259, has hit a dead end. The kinase inhibitor was the Belgium company's lead candidate and positive data could have triggered a €60m signing fee with partner Johnson & Johnson, so disappointment is understandable.

However, although the loss of GLPG0259 is a setback, Galapagos is a lot more than just this product - multiple research deals in place means the company has turned a profit for the last two years, and a large if very early stage pipeline is making good progress. With further milestones payments on the horizon and new deals being sought, Galapagos' punishment looks overly harsh.

Big potential

A decision to end the GLPG0259 study was taken after results from the first 30 patients taking part in a phase II were unblinded by an independent panel. No safety issues were seen, but neither were any encouraging efficacy signals.

Given growing hopes around new small molecules approaches to treat RA, in particular the several kinase inhibitors which are making progress through the industry's pipeline, investors had been getting excited about GLPG0259, despite its early stage. The MAPKAPK5 inhibitor was a first-in-class protein kinase candidate with a novel mode of action, thought to play a key role in inflammation and in the breakdown of collagen in human cartilage.

Pfizer's success with tofacitinib has established kinase inhibitors as potentially clinically and commercially valuable new oral therapies to treat the autoimmune condition. With J&J already owning an option, clinical success with GLPG0259 could have been a game changer for Galapagos (*Therapeutic focus - Pfizer data highlights potential of JAKs in arthritis, November 11, 2010*).

Not to be deterred, the company said today it still has 11 candidates identified as potential new RA drugs. The most advanced, GLPG0634, is a JAK inhibitor, still fully owned and ready to enter phase II; proof of concept data is due later this year.

Talks are under way with partners, chief executive Onno van de Stolpe said today on a conference call, and a deal will be sought before taking the drug any further.

Big event

This data for GLPG0634 now becomes a big event for Galapagos on the horizon. However, a number of other milestones will be reached this year, under the myriad research partnerships the firm has signed over the last few years.

These alliances are the engine room for Galapagos, providing funds for its own research. The company's services division conducts drug discovery functions for clients, including biologic target discovery and screening and medicinal chemistry. This unit has been bolstered by two acquisitions – BioFocus and Argenta – which allows the company to offer services from target discovery through to the delivery of pre-clinical compounds.

The option owned by J&J over GLPG0259 was part of two RA alliances the firms have in place. The US company is actually Galapagos' second biggest single shareholder, with a 8.9% stake purchased as part of the deals. Other accords include two separate research alliances with GlaxoSmithKline, in osteoarthritis and anti-infectives – important phase I proof of mechanism data is due on the most advanced candidate from the anti-infectives collaboration towards the end of the year.

Galapagos also has research deals in place with Eli Lilly, Servier, Roche and Morphosys, as well as internally generated candidates for which partners will be sought, in cancer and cachexia. The grandest internal ambitions lie in cystic fibrosis, where the company believes it has identified the potential for a disease modifying therapy, and which it wants to take all the way to market.

Into the black

Progress with these collaborations have yielded small but helpful milestone payments over the last few years, so helpful that the company moved into the black a year earlier than anticipated, posting its first profits in 2009, and again in 2010. The company generated revenues of €137m last year, ending 2010 with €40m in the bank.

With the loss of GLPG0259, Galapagos is left with only four phase I candidates, and a bulging research-stage portfolio – 58 candidates are heading towards the pre-clinical stage.

Although it has many shots on goal, this is undeniably a high risk, early stage pipeline. But there is a good chance GLPG0259 will soon be replaced.

Galapagos shares had plunged to €9.30 in late trading, a price last seen in January 2010. Real value still exists in Galapagos' labs and shareholders are unlikely to be tapped for cash anytime soon, making the chances of a stock market recovery look good.