Evaluate Vantage

February 06, 2013

Merck KGaA deal only a stopgap solution for Opexa

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It took Opexa Therapeutics more than two years, a rebranding, a reverse stock split and $13m in fund-raising to deliver a deal on its lead product, the multiple sclerosis immunotherapy Tcelna. And while excited investors more than doubled the share price in yesterday's session, there is no doubt that the small option with Merck KGaA will be insufficient to get the Texas group even to the end of phase II.

Executives at Opexa acknowledged that even with the $5m upfront it will only have sufficient cash to get through the third quarter of 2013, long before the readout on the current phase IIb trial due in 2015. A fund-raising is certain, and given yesterday's share rise this will come sooner rather than later.

A big if

The terms of the deal are fairly generous – if the German partner comes through with a licensing deal following positive phase II data. An opt-in would see the owner of Rebif also pay a $25m licensing fee and up to $195m in milestones, of which $110m are based on clinical and regulatory achievements. Merck would also assume phase III costs.

Tiered royalties ranging "from the high single digits to the mid-teen" percentages are also due on sales, chief executive Neil Warma told investors. Opexa also has co-development option, which would change the economics of the deal. The Texas group retains rights in Japan and in indications outside MS.

Opexa's challenge is the estimated $15m cost of the trial. At September 30, 2012, the company had $2.2m. Since then it has raised an additional $1.7m; with the additional $5m, Mr Warma said the company had sufficient funds to last through the third quarter, but a fund-raising would be necessary to get the phase IIb Abili-T trial to the finish line.

The company has arranged with Lincoln Park Capital Fund to sell up to $16.5m in shares over 30 months. But because this agreement caps the fund's total ownership to less than 15% of the company's shares in issue, Opexa has limited manoeuvring space.

Thus, yesterday's 160% uplift in the share price to $3.15 sets the stage for a public offering. Share dilution would no doubt be disappointing to investors – who no doubt see it coming now, given the intraday high of $5.05 shortly after yesterday's opening bell – but it would give Opexa more cushion to turn on the tap of the Lincoln Park deal at a later date.

Indeed, shares had fallen back to $2.95 in early trading today.

Personalised care

Tcelna was formerly known as Tovaxin, and is an autologous immunotherapy that aims to suppress T-cells that attack myelin in MS, leading to neurodegeneration (*EP Vantage Interview – Opexa touts potential of disease-modifying MS drug, January 11, 2011*). Essentially, reactive T-cells are taken from patients, irradiated and then reintroduced into patients to stimulate an immune response from the regulatory T-cells to modulate the autoimmune response.

Tcelna's manufacture has similarities to Dendreon's prostate cancer immunotherapy Provenge, which has disappointed since its launch in 2010. Immunotherapies might be better suited for diseases where progression is slow, such as MS, rather than the very sick prostate cancer patients that Provenge aims to treat.

The phase IIb Abili-T trial initiated in September 2012 plans on enrolling 180 secondary relapsing MS patients and test two annual courses of five subcutaneous doses of Tcelna against placebo, with brain atrophy measures at 24 months the primary endpoint.

Opexa has completed the phase IIb Terms trial in the earlier-stage relapsing remitting MS, and Mr Warma declared it to be ready for a pivotal study. However given the novel approach it is not surprising that the German partner is interested in seeing more from the product, particularly as the MS field is about to see a major new entrant in the shape of Biogen Idec's all-oral BG-12.

Getting a pharma partnership, even if it is an option deal, is a useful step forward for a company as small as Opexa and a product as unusual as Tcelna. It is far too soon to declare it a win, but there can be no doubt that Merck's opt-in fee, and the resulting share rise, have given Opexa some breathing room.

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