

Imugene

Progressing HER-Vaxx into a gastric Phase II

Imugene is developing a Phase II in second-line cancer for its acquired HER-Vaxx therapeutic vaccine targeting HER2+ gastric cancer patients. HER-Vaxx may replicate the antibody combination of Herceptin and Perjeta (Roche) that shows impressive survival efficacy in breast cancer. Gastric cancer is seen as a more promising large, poorly-served market. Phase I (in breast cancer) showed safety with the virosome-based vaccine stimulating good antibody responses in eight of 10 patients. The Phase II trial will take two years to run and cost A\$3-5m with the aim of gaining a major deal from 2017.

HER-Vaxx design

HER-Vaxx is three linked HER2 peptides integrated into a flu-derived virosome. The immune system usually responds strongly to flu, creating therapeutic antibodies to the HER2 target potentially with linked activation of white immune system cells. HER2 is overexpressed in 20% of gastric cancers. The 10-patient safety Phase I in 10 HER2- breast cancer patients showed that eight developed antibodies.

From breast to stomach

HER-Vaxx targets both the Herceptin (trastuzumab) and Perjeta (pertuzumab) HER2 binding sites. In metastatic breast cancer, a Herceptin-Perjeta doxorubicin combination improves survival over Herceptin alone: hazard ratio of 0.66. (Herceptin is indicated in gastric cancer but the combination is not tested.) In the HER-Vaxx Phase II, about 70 patients will be divided into two arms; both get standard of care with one getting HER-Vaxx and one placebo. The endpoints will be overall survival and disease-free progression. The trial could report in H217 if it starts in H115.

Gastric offers more opportunity and faster data

First-line gastric cancer therapy with capecitabine only gives a 10.2-month median survival vs 9.2m on palliative care. Globally, there are about 0.9m cases per year, many caused by chronic stomach infection with the bacterium *H. pylori*. Incidence is weighted towards Asia and less developed countries. There were 13,230 cases in the US in 2012; EU incidence will be similar; Japan has four times the US incidence rate. The Herceptin-Perjeta combination costs over US\$100k per year; Her-Vaxx could be similar. This implies a final market, excluding China and developing countries, of over US\$500m at 40% market penetration and 20% HER2 prevalence.

Valuation: A novel approach with deal potential

HER-Vaxx offers a validated antibody concept compared with T-cell vaccines like NeuVax (Galena/Genentech; aimed at breast). If its Phase II succeeds, HER-Vaxx could gain a big pharma partner. In 2013, AstraZeneca paid \$225m plus milestones of \$275m for Amplimmune's Phase I PD-1 antibody. Cash was A\$1.2m on 30 June.

Historical financials

Year end	Revenue (A\$m)	PBT (A\$m)	EPS (A\$)	DPS (A\$)	P/E (x)	Yield (%)
06/13	0.21	(1.6)	(0.48)	0.0	N/A	N/A
06/14	0.53	(2.1)	(0.31)	0.0	N/A	N/A

Source: Company reports. Note: Income includes interest and R&D tax credit refunds.

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Price **A\$0.016**
Market cap **A\$15m**

Share price graph



Share details

Code **IMU**
 Listing **ASXN**
 Shares in issue (bn) **946.5m**

Business description

Imugene restructured into a cancer vaccine business with the acquisition in December 2013 of HER-Vaxx, a proprietary HER2 +ve cancer vaccine that stimulates a polyclonal antibody response. A Phase II is planned in gastric cancer potentially reporting in 2017. The drug delivery business has been mostly written off.

Bull

- HER-Vaxx stimulates the antibody response as an alternative approach to T-cell vaccines like NeuVax. It has patent protection until 2030.
- Limited gastric competition with high unmet need. Market of 930,000 cases a year, so good partnering potential following Phase II efficacy.
- Phase I data showed responses in eight out of 10 patients with response linked to the flu-based virosome immune response.

Bear

- HER-Vaxx has a long history and excellent Phase II data is needed to attract a Phase III partner.
- Imugene will require up to A\$5m cash to fund the study; Australian R&D tax refunds will help.
- High-priced (US\$100k) market is limited. Main volume markets are China (0.35m cases) and less developed countries.

Analysts

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