

EP Vantage Interview - Immatics readying second late-stage cancer vaccine



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The emergence of more encouraging data on Immatics's colorectal cancer vaccine means the private German drug developer could soon have a second immunotherapy being tested in a randomised, late-stage study.

A phase III trial is already underway with its renal cell carcinoma candidate, testing whether the vaccine can extend the life of patients being treated with Sutent. Phase II data presented at Asco this year pave the way for further testing of the company's renal cell cancer vaccine, chief medical officer Carsten Reinhardt tells *EP Vantage*. Talks are underway with interested parties to determine whether the path forward will be alone or with a partner, he says.

Matched pair

At this year's Asco conference Immatics presented a "matched pair" analysis that compared the performance of patients in a phase II study it conducted with its product, IMA910, and certain patients that took part in the Coin study. Conducted by the UK's Medical Research Council several years ago, the large phase III Coin trial was designed to test Erbitux's impact on the survival of patients with colorectal cancer.

The trial contained a control arm of patients very similar to those recruited for Immatics' study - they were unsuitable for surgery and were treated with the same oxaliplatin-based chemotherapy schedule - and essentially provided a control arm for '910.

The analysis conducted by Immatics found that the overall survival of patients treated with IMA910 was significantly longer than the matched patients in the Coin study - 19.7 months compared to 16.5 months. The patients treated with IMA910 also had higher one-year - 69% versus 55% - and two-year - 40% versus 24% - survival rates.

"The survival curves really start to separate after 6 to 9 months, which is very typical of immunotherapy," Mr Reinhardt says. "The longer you follow up the better the outcome for our trial, compared to the Coin trial."

Biomarkers

The phase II study also confirmed what the company saw with its renal cell candidate (IMA901) - that those patients with a measurable immune response to the vaccine lived longer.

"Only the immune responders do better than the Coin patients. After more than two years we still hadn't reached median overall survival in the responders," Mr Reinhardt says.

Correlating survival to those with a measurable immune response is important in many aspects - it is something that Dendreon never managed to do with Provenge, for example - as it not only demonstrates the drug is doing what it is designed to do, but can help identify patients likely to benefit from the therapy.

This evidence in turn makes expensive late-stage studies more likely to succeed and will smooth the path of a product going in front of regulators and, with ultimate success, payers.

Immatics has identified the biomarkers it believes can spot patients more likely to respond to '910, although it has not disclosed them yet. Biomarkers are being collected as part of the phase III trial of its renal cell carcinoma product, '901. The two most promising serum markers - CCL17 (TARC) and apolipoprotein A1 - are being validated as part of the study.

"We cannot say 100% [that patients with these markers] will respond but they have a higher likelihood," Mr Reinhardt says, saying he expects a similar technique will be employed as '910 progresses into larger studies.

Path forward

What exactly the larger study will look like has yet to be confirmed. The company plans to consult with experts in the US and Europe before finalising plans, Mr Reinhardt says. How it will be funded has also to be decided.

“We can imagine two pathways – doing it ourselves or finding a partner. We are talking to various companies because colorectal cancer is such a big indication and having a partner would be more likely to exploit the potential of ‘910. So both are feasible, but we are talking to partners.”

The company is collaborating with Pfizer on the 300-patient phase III renal cell study, although the terms of that have not been disclosed other than stating that the pharma giant is providing Sutent to all the patients enrolled. The company hopes to show that adding ‘901 can substantially prolong survival. Patients with advanced renal cell carcinoma treated with Sutent are expected to live 22-23 months. Results are not likely to emerge until later next year.

Immatics raised a substantial \$70m Series C round in 2010; however, running two late-stage cancer studies will not come cheap ([*Immatics' cancer vaccine platform receives €54m vote of confidence, September 21, 2010*](#)). Bringing on a partner would help the cash last longer while positive data from the phase III ‘901 study would in turn help attract those interested parties.

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