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EP Vantage Interview – Immatics ponders cash call as data approaches

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Some critical milestones in the development of Immatics Biotechnologies' renal cell carcinoma vaccine IMA901 are now in sight, with an interim look due a year from now and final data in 2015. And after raising €108m ($147.3m) in three funding rounds, the private German biotech will probably need to pass the hat one more time before it reaches those goals.

Chief executive Paul Higham tells *EP Vantage* that the Tübingen-based company is funded until the end of 2013, so it is now in talks with current investors to extend its cash runway with a follow-on round, likely this year, the amount of which has yet to be determined.

"They're committed to fund the study," Mr Higham says of Immatics' current investors. "We think it's very unlikely we'll bring in new investors. I think our strategy is completely in line with what our investors want to see, which is get through to the data from the phase III trial.

"It could be that the interim data allows us to do something with the project such as partnering that will bring a lot of money in," he says.

Hopp to it

With the presence of the German tech player Dietmar Hopp among Immatics' investors, raising that extra cash will likely necessitate a yes from the billionaire. The last fundraising was a €54m round in 2010, specifically to underwrite the costs of '901's pivotal trial (*Immatics' cancer vaccine platform receives €54m vote of confidence, September 21, 2010*).

The group has a number of balls in the air that have made a demand on its resources: mid-stage work for the colorectal cancer vaccine IMA910 is also under way, with recruitment in a phase IIb first-line study mooted for the end of 2013. Cancer Research UK, meanwhile, is backing a phase I trial of a glioblastoma vaccine, IMA950. This is currently funded by the charity, with Immatics having an option to license it back if data are positive.

All three have been developed using the group's proprietary platform, which relies on stimulating a T-cell response through identification of multiple human leukocyte antigen (HLA) peptides on the surface of tumour cells. Mr Higham said Immatics had learned from previous cancer immumotherapy failures by using multiple peptides: in the case of IMA901, there are 10 such peptides.

Adjustments

Cancer immunotherapies have a patchy track record – so far just one, Dendreon's Provenge, has made it to the market and only then after getting a first-cycle rejection in the US. Merck KGaA and Oncothyreon's Stimuvax is just the latest failure (*Stimuvax doomed in lung cancer, December 19, 2012*).

What is telling about cancer immunotherapies is the lack of big pharma presence in the space right now. Other than Otsuka and Shionogi, no big names can be identified backing such products in clinical development, even though *EvaluatePharma* shows that there are three vaccines in late-stage development to which analysts have attached forecasts.

Part of the disappointment is cancer cells' cunning in evading the body's immunological response. "Other companies have tended to take the easy route and say, 'OK, it's known that antigen one is overexpressed in cancer cells. We'll use that antigen and try to create a cancer vaccine,'" Mr Higham says. "Other people have tried to predict which targets will be relevant to cancer cells. We think that is a very risky thing to do.

"Sometimes they're just done the wrong studies, looking at the wrong endpoints: progression-free survival instead of overall survival, which is the key endpoint for immunotherapy. As a company I think we've looked at and learned from the lessons of the past."

Clinical, regulatory and commercial matters

Immatics' own interactions with the FDA have been straightforward, Mr Higham says. The company did not seek a special protocol assessment for '901's phase III trial because its primary endpoint of overall survival is clear and because it has been able to demonstrate that patients with an immune response perform better. The OS endpoint helps explain the length of the clinical development.

Helping the vaccine's case will be two predictive biomarkers, identified in a Nature Medicine article as apolipoprotein A-1 and chemokine ligand 17, which should help ensure that the right population can be identified should '901 make it to the market.

And in the case of trial success, the company is looking for a takeout or commercial partner. Mr Higham believes Immatics will not be able to file on the pre-specified interim results next year, but the data could drive a collaboration. Solo commercialisation or an initial public offering are not likely.

Failure, on the other hand, will raise another host of issues. Without the validation that success for '901 would bring, the colorectal cancer vaccine '910 will probably have more difficulty in the partnering derby – the company certainly would be in a weaker position to demand favourable terms. Going to phase III unpartnered, on the other hand, would require another fundraising round.

Despite the bad news on cancer vaccines, Immatics and other biotech developers continue to soldier on. In the coming year we could find out whether the German group is giving a breakout performance or whether IMA901 is destined for the cancer vaccines' expanding graveyard.

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