Evaluate Vantage

July 06, 2015

Interview – US placement reanimates Neovacs into lupus play

Jonathan Gardner

Coming off the year-end failure of its lead project, Neovacs provides more evidence that there are second chances in biotech if one can find the right risk-inclined investors. The French group found a lifeline for the next 12 months through a €7.5m ($8.3m) private placement with three US institutional investors, following a now well-trodden path of companies that have battled the scepticism of European investors.

“We had no problem raising this money in the US”, chief executive Miguel Sieler tells *EP Vantage*. “American investors had a totally different approach. They said, ‘There is no biotech company in the world that has become successful which in its history has not one failure in its learning curve. You have the failure behind you. So now you are in the success part of your learning curve’.”

Starting over

With failure of the rheumatoid arthritis project TNF-Kinoid at the end of 2014, Neovacs saw its valuation crash (*Cyclacel and Neovacs enter the graveyard shift, December 24, 2014*). The group’s focus has turned to lupus, with the project IFNα-Kinoid advancing in midstage trials as an immediate benefit of the new funding.

The Paris-based group’s technology seeks to stimulate an immunotherapeutic response by linking a carrier protein called keyhole limpet haemocyanin to an inactivated cytokine – interferon-alfa in the case of the lupus project. Paired with an adjuvant, the agent becomes a therapeutic vaccine that it is hoped will stimulate production of antibodies to modulate the dysregulated protein.

The advantage of this approach is that the antibodies Neovacs has been able to stimulate are polyclonal, binding on multiple epitopes, while the monoclonal antibody that has entered the market in lupus, GlaxoSmithKline’s Benlysta, binds to only one. Furthermore, Mr Sieler says its agents can provoke a sustained immunological response with few injections, while Benlysta requires monthly injections.

Given that Neovacs presented phase I/II data from IFNα-Kinoid nearly four years ago, it is surprising that it has not advanced further. Mr Sieler says that was the result of a decision to prioritise the now-failed rheumatoid arthritis project.

Interferon-alfa was believed to be a good target for lupus treatment at that time, but it had yet to be validated by clinical trials. “For that reason, hoping to minimise the risk, Neovacs took the decision to develop TNF-kinoid in rheumatoid arthritis”, he says.

Since then AstraZeneca has generated positive data for its interferon-targeting antibody anifrolumab, advancing it into phase III. A second Astra antibody called sifalimumab has also performed well in phase II.

Hoping to partner

Indeed, these are just two agents in a growing big pharma pipeline of biologicals nearing key pivotal data points; Benlysta was the first new lupus treatment in 50 years, though projects like UCB’s epratuzumab and Merck KGaA’s atacicept have proceeded slowly.

The late-stage pipeline is dominated by big pharma and biotech, so Neovacs will have its work cut out. All of which is why Mr Sieler is eager to talk about what he hopes is a sustained therapeutic response.

“We know we can divide the annual treatment costs of today at least by three or by four. I’m not making the price policy of the future, but economically this could be feasible. Even biosimilars of the monoclonal antibodies are not a threat for us,” he says.

To get to a stage where price competition is a worry, Neovacs needs IFNα-Kinoid to perform in the clinic. The cash infusion – which came from “NY-based investment funds specialised in biotech” that Mr Sieler would not name – will be used to fund a global phase IIb trial in 166 patients to begin later this year, and a US-based phase IIa trial in 60-80 that will begin six months later.

He says the cash will be sufficient to fund the group for another 12 months without having to tap an equity line with the investment bank Kepler Cheuvreux. In that time, Neovacs will seek regional licensing pacts, particularly in Asia – Mr Sieler is enthusiastic about a South Korean partnership, as lupus is an orphan disorder there and IFNα-Kinoid might be able to win approval on phase IIb data.

Neovacs has a new lease of life, but, as a sign of how far it has to go, shares have not enlivened much on news of the new funding. Having a therapeutic approach that holds the promise of changing treatment paradigms, however, Neovacs has a shot at winning more converts.

To contact the writer of this story email Jonathan Gardner in London at jonathang@epvantage.com or follow @ByJonGardner on Twitter