Evaluate Vantage

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EP Vantage Interview - Neovacs seeking partners for autoimmune vaccines

Jonathan Gardner

With one candidate about to report phase II data in rheumatoid arthritis (RA) and a phase II trial about to begin for a second in lupus, France's Neovacs is hoping to secure a partner soon to finance pivotal trials for its novel immunotherapeutic approach to inflammatory disease.

Speaking with *EP Vantage*, chief executive Guy-Charles Fanneau de la Horie said he is in the process of seeking a partner for one of its two therapeutic vaccines, which rely on stimulating an immune response to the dysfunctional cytokines that cause RA, lupus and a host of other inflammatory diseases.

Should firm deals emerge, the French group would need to consider the advantages of partnering only one, and using the licensing fees to finance the remaining pipeline, he said.

“What we are looking at is making one deal for one product. This deal would need to be structured in a way to allow us to develop the second product," Mr de la Horie said in an interview at the American College of Rheumatology (ACR) meeting earlier this month in Chicago.

However, if attractive offers came in for both, he says the company would still partner both. "We would be very practical."

Combating cytokines

Overproduction of cytokines is one of the signatures of autoimmune disorders like RA and lupus. In the case of RA, tumour necrosis factor-alpha (TNFa) is the culprit, whilst interferon-alpha is linked to lupus.

The leading biological drugs in both conditions – Humira in RA and Benlysta in lupus - are monoclonal antibodies, which bind at a single epitope on the cytokine. Resistance to antibodies can develop, however, so drugs that are less prone to resistance are needed, Mr de la Horie said.

Neovacs has taken the approach that stimulating the factors that naturally downregulate cytokine production may be a more effective approach.

“The immune system has the capacity to produce antibodies that will neutralise these cytokines,” Mr de la Horie says. “Our bodies do consider the cytokines as normal. They don’t fight against them even when the body is dysregulated."

Neovacs’ technology creates a structure called a kinoid, a de-activated cytokine that the body will recognise as foreign. It is hoped that the resulting immunotherapy can stimulate a natural response to these damaging cytokines, creating a therapy less vulnerable to resistance and effective in a wider patient population.

Early returns

So far the RA drug, partnered with Debiopharm through to the end of phase II, has reported positive early phase II data; 11 of 21 patients who have failed on at least one TNF-alpha therapy dosed with Debio-0512 developed anti-TNF antibodies. Six of the 11 saw a 20% decrease in signs and symptoms of RA, compared with just two of the ten who did not develop an immune response.

That trial is expected to report full phase II data in December, with a second trial in Crohn’s disease recruiting and expected to report data in the first quarter of 2012.

The lupus drug, IFNa Kinoid, reported phase I/II data at ACR; it showed that all 28 patients dosed with the immunotherapy developed an immune response to interferon alpha, while it had a statistically significant effect on the genes related to interferon alpha and those related to lupus disease.

Mr de la Horie said the company is now developing plans for a phase II trial that could number as many as 100

or 150 patients. Recruitment is expected to begin at the end of the first quarter or the beginning of the second quarter next year.

Funding concerns

Neovacs, which floated in April 2010 at €4.80, is funded through October 2012, Mr de la Horie said. Hence the need to come up with a partnership in the near future. The company did three fundraisings earlier this year, netting just over €10m and leaving it with €15.3m at the end of June.

Shares stood at $3.18 in mid-afternoon trading today, off the €5.12 record achieved in June but still up 38% on the year. The company is currently valued at €50m.

He did not put a timeframe on the deal, saying further share sales could help the company get past the October 2012 date if necessary.

“We will not drop products,” he says. “We are very confident we will be able to fund the next steps. We are producing very interesting products; we believe that this is not yet fully valued by the market. It’s up to us to make sure everybody understands the value of the data we are presenting.”