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# Interview – Abivax not getting ahead of itself in HIV chase

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A doubling in valuation based on positive trial data is the sort of catalyst many small biotechs use to raise a new pile of money. Not so the French antiviral specialist Abivax, which is taking a deliberate approach after an early phase II trial found evidence that ABX-464 reduces HIV reservoirs in humans.

The group has a cash runway to last through the middle of 2018, which will allow it to see through another phase II study aimed at further understanding the project's effect on viral reservoirs. Findings from that trial, due to emerge later this year and early next, should guide design of pivotal studies to determine how best to use ABX-464 in concert with other HIV drugs, with the hope of, at a minimum, being able to reduce exposure and limit side effects.

"Some patients now have 20 years on triple therapies," Jean-Marc Steens, Abivax's chief medical officer, tells *EP Vantage*. "The virus is well-controlled, but now we see other co-morbidities.

"What could be an option is we have treatment free-periods, and as with oncology give [antiretroviral treatments] in cycles," Mr Steens says. "That's why we call it functional remission. That would be a major step forward."

**Elite control?**

Phase IIa data provided some reason for optimism. The trial in 30 treatment-naïve patients tested ABX-464 or placebo on top of boosted darunavir for 28 days, then on the 29th day interrupted treatment of all drugs to measure viral load rebound, as measured by copies of HIV DNA in peripheral blood mononuclear cells (PBMCs).

Among 14 evaluable patients taking ABX-464, seven responded, as defined by a reduction of more than 200 copies of HIV DNA per million PBMCs at the end of follow-up, compared with no responders among the four placebo patients. This reduction in viral load in PBMC is a sign that its candidate is reducing HIV reservoirs and could alter the course of the disease, Abivax believes.

"What we aim for is to get to a stage of long-term suppressors, or elite controllers," Mr Steens says. These patients maintain low viral load long after being infected, though it is not clear why – reduced levels of inflammation is one hypothesis.

It is too soon to declare that ABX-464 can achieve this, of course, but the continued refinement of treatment protocols in phase II will help Abivax and its potential partners think about how they might meet that lofty goal in pivotal trials.

Thus, a phase III design is not at the forefront of the group's mind. The findings from the latest trial measuring HIV in blood have enabled it to amend a second phase II trial studying ABX-464's effect on HIV reservoirs, this time in gut tissue.

That trial's first cohort, which started in March, is also undergoing 28 days of treatment, and results from those patients should be available in the third quarter of 2017. Now with the blood data available, Abivax is submitting a protocol amendment to the gut trial to be extended to three months of treatment – the three-month cohort is set to begin in September – and may soon be able to treat for up to six months, Mr Steens says.

**Onward**

From there, the group will begin looking at a phase IIb trial, and from there plan a phase III trial at the end of 2018, he says.

Announcement of the data earlier this month saw Abivax's valuation rocket from €89m to €190m, although it has fallen back a bit since. The company has so far not announced a fundraising, although Mr Steens says the group has been talking to both potential partners and to banks.

At year end 2016, Abivax had €23m ($26m) in cash after spending €16m during the year, putting it in a position to complete the phase II work and plan phase III in 2018. To put the candidate into late-stage clinical trials, of course, would require more money or a partner – to that end, Mr Steens says the group has shown the data to the big HIV companies.

“Our strategy today is to try to progress the drug as much as possible ourselves in order to increase the value,” he says. “We’re not in a hurry to partner.”

| Trial | ID |
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| ABX464-004 | NCT02735863 |

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