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Valneva forgets Pseudomonas vaccine

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GlaxoSmithKline looks likely to take another step away from French vaccine developer Valneva. The UK-based company had already waived option rights to Valneva's *Clostridium difficile* vaccine VLA84 for "strategic reasons", and will now probably shun its *Pseudomonas aeruginosa* vaccine candidate VLA43 after its failure in a phase II/III trial.

More data should be available in the coming months, but a spokesperson for Valneva told *EP Vantage* that the company expects to discontinue the programme. Valneva says it does not expect the shuttering of the vaccine to affect its strategy; it has two commercial vaccines which brought in sales of $83m last year. As for R&D, it plans to focus on the phase III-ready *C difficile* vaccine and two products set to go into phase I soon.

This was not enough to placate investors. The French group's stock crashed 19% on Friday and was down another 4% during trading this morning.

Valnevamind

The failure of the 800-patient phase II/III trial to meet its primary endpoint – the number of deaths at 28 days versus placebo – is not only a blow to Valneva, but also to efforts to combat hospital-acquired infections. According to *EvaluatePharma*, no other prophylactic vaccines against the bacteria are in clinical development.

Valneva did not report any data from the study, but did also say that overall survival, a secondary endpoint, did not differ between the treatment and placebo groups.

The company had been hoping to use the trial to support approval, or at least as the basis for a pivotal phase III trial, but even the latter now looks out of the question; Valneva conceded it is unlikely that Glaxo will exercise its option to the programme.

VLA43 had previously been partnered with Novartis under a 2007 deal, but was transferred to Glaxo in last year's asset swap.

Glaxo has already decided it wants out of another partnership inherited through the Novartis deal: that covering Valneva's prophylactic *C difficile* vaccine VLA84. The French group is now looking for another partner and expects to have one in place by the end of the year.

In November, it reported that a phase II trial of VLA84 had met its primary endpoint, identifying the dose with the highest seroconversion rate, but did not disclose any data. The study is expected to close around mid-2016 – perhaps any potential collaborators are awaiting more details before taking the plunge.

Earlier in development are its Lyme disease and Chikungunya vaccines, set to go into phase I by the end of the year and 2017, respectively. "We are also currently finalising proof of concept experiments to develop a Zika vaccine... and expect to announce results in the coming months," the spokesperson added.

Valneva believes it will come close to break-even in 2016, with forecast sales of nearly €100m representing 20% year-on-year growth. It already markets a Japanese encephalitis vaccine, Ixiaro/Jespect, and Dukoral, a vaccine against cholera and diarrhoea caused by enterotoxigenic *Escherichia coli*.

Valneva seems sure that the VLA43 failure is a hiccup rather than a disaster. But vaccines for anything other than childhood diseases are increasingly looking difficult to develop. The company will hope the rest of its pipeline does not go the way of VLA43 – or it will have a bigger problem on its hands.

Drug	Trial	ID
VLA43	Phase II/III study	NCT01563263
VLA84	Phase II study	NCT02316470

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