Evaluate Vantage

September 13, 2021

# Valneva falls as UK contract axe falls

Lisa Urquhart


## Valneva might have to look beyond the UK for vaccine sales after today's contract termination.

If the UK government's agreement with Valneva was partly about ensuring a domestically available source of vaccines, then the announcement of the termination of the deal with the French company has almost certainly torpedoed that goal.

The early stages of the pandemic, marked by vaccine nationalism and the scramble to get hold of scarce vaccine supplies, demonstrated just how easily protectionism could destroy international supply chains.

So the agreement between France's Valneva and the UK government not only to procure 100 million doses of Valneva's VLA2001 Covid-19 vaccine, but also to build a manufacturing site in West Lothian, Scotland, was seen as a way for the UK to secure vaccine supplies for future pandemics as well as Covid-19.

**Thanks, but no thanks**

But today Valneva said it had received a termination notice from the UK government over an alleged breach of "its obligations under the supply agreement", an allegation it denies. Valneva's shares fell 39% today.

The news caught many in the industry by surprise given the UK government's initial enthusiasm for the project and VLA2001's potential to cope with variants. With no statement from the government as to what the breach of obligations are, some have looked at the financial terms of the deal.

Stifel analysts noted that as of June 30 Valneva had received around €338m ($399m) from the UK government, recorded as contract liabilities, which are not repayable on termination, or if the vaccine fails. The sums are repayable if there is a breach of contract.

**Full steam ahead**

In its statement Valneva vowed to press on with developing VLA2001, and phase 3 results are due in early October, but at the moment the options for the vaccine appear limited.

Valneva's pivotal trial will compare the immune response with VLA2001 versus that seen with Astrazeneca's Vaxzevria in 4,000 UK participants, a move partly necessitated by the difficulty of finding unvaccinated trial subjects in accessible countries.  And while it is increasingly accepted that antibody response correlates to efficacy it is unclear how regulators outside the UK, where the trial was designed, might view this surrogate endpoint.

Valneva could file in Europe, but even under EU conditional approval VLA2001 might not make it to the market until next year. Any route into the US remains closed, as VLA2001 is being compared against a vaccine that is not approved there. This only leaves UK approval through the MHRA.

**Going global**

The MHRA is an independent body, so notwithstanding the decision by the UK government Valneva could still get UK approval by the end of the year. This in turn could lead to WHO approval and, more importantly, acceptance into the Covax programme.

This must surely be the route that Valneva is now looking at given the need for vaccines in low and middle-income countries. The group would also be wise to start looking at potential licensing partners for its now spare vaccine manufacturing capacity.

As for the UK's future pandemic preparedness, who knows.