

## Mitsubishi's Medicago readies for the second wave



Amy Brown



### **Awaiting crucial pivotal data, company reckons its plant-generated Covid-19 vaccine can still make a contribution to the pandemic.**

Alongside rollout of the first generation of Covid-19 vaccines the next wave of shots is being pushed through the clinic. These will help supply global markets and meet demand for the boosters thought likely to be required in the coming years, and it is here that Mitsubishi Tanabe's Canadian subsidiary Medicago hopes to step in.

Its project is one of two novel jabs currently in late-stage trials using a Glaxosmithkline adjuvant; the other, developed under a Sanofi-Glaxo collaboration, [moved into phase 3 yesterday](#). Medicago is well ahead of these giants of the vaccine world, however, and remains confident that its pivotal trial will read out by the end of summer, the division's chief medical officer, Brian Ward, tells *Evaluate Vantage*.

It was decided not to take an interim look at the results, Mr Ward says, so when news emerges it will be the final readout, planned at 160 infections. The trial was powered to show 65% efficacy.

"If we are higher than that - which we hope we will be - we will have a considerable confidence in the efficacy estimates because we will have far exceeded the numbers we needed to demonstrate that relatively low efficacy," Mr Ward says.

[The trial is seeking around 30,000 subjects](#) and Medicago hopes to reach 5,000 enrollees this week. Recruitment in Brazil and Mexico started last week, joining sites in the US, UK, Brazil and Canada, and several more Central and South American countries will soon be added.

"The Southern hemisphere is going into its winter season, so attack rates are expected to go up," Mr Ward says. This provides confidence in quickly hitting the required number of infections. If efficacy is demonstrated, all placebo subjects will immediately be offered the vaccine.

### **Proof of principle**

Should Medicago's efforts succeed, its triumph ahead of huge vaccine developers will be even more remarkable considering that the company has yet to get a product to market. Its lead asset, [a flu vaccine](#), is in front of Canadian regulators.

Another notable point is the company's technology: its vaccines are grown in plants. This process involves

introducing a viral gene sequence into a plant-specific bacterial vector, to which *Nicotiana benthamiana*, a type of tobacco plant, are then exposed. Acting like a bioreactor, the plants' cells produce huge quantities of virus-like-particles in a matter of days, and these can then be harvested.

"It's a simple series of centrifugations and filtrations to get these very consistent virus-like-particles in a remarkably pure preparation. It's quite elegant, and there really is very little contamination of other plant proteins and membranes so on," Mr Ward says.

The UK's MHRA, US FDA and the Canadian regulators have all granted the Covid-19 project fast-track status, with preclinical and manufacturing data already being submitted under rolling reviews. This would not have been permitted if any agency had any hesitations with the platform or the product, Mr Ward says.

He admits, however, that for now Medicago is capacity constrained, at 100-200 million doses a year. This ruled it out of Warp Speed funding, Mr Ward says, which required existing capacity to produce half a billion doses. A plant to take manufacturing to that level comes online in late 2023.

Medicago started out as a small biotech, but [sold a 60% stake to Mitsubishi Tanabe in 2013](#). The tobacco giant Philip Morris owns the remainder, and both have provided extra funding for the Covid-19 project, as well as the Canadian government.

### Field proof

The remaining hurdle is proving that the Covid-19 project works. [Phase 2 data](#) were encouraging, with two doses producing neutralising antibody responses 10 times higher than in people recovering from Covid-19. This is higher than seen with some other projects, Mr Ward points out, and should position the vaccine as a strong contender as a booster.

Evidence is increasingly pointing to the need to maintain high levels of antibodies to guarantee crossreactivity against new viral variants. *In vitro* testing of the project against the South Africa variant is ongoing, Mr Ward says, with data due in the coming weeks.

The vaccine was designed to defeat the original Wuhan strain, against which he hopes to see efficacy up in the 80s.

"We will take a hit against the South African and Brazilian variants, but maybe not as much as others have," he says. "But it's one thing to show it in a test tube. The proof is in the field."

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