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Arcturus to test single-dose vaccine in large phase 3 trials

US-based firm developing vaccine with Duke-NUS plans trials in three locations in Q2

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United States-based Arcturus Therapeutics, which is jointly developing a Covid-19 vaccine with the Duke-NUS Medical School in Singapore, is preparing to test a single low-dose shot of its messenger RNA vaccine in large trials that will start in the second quarter of the year.

The 5 microgram single-dose regimen will also be a lyophilised, or freeze-dried, version that will be easier and less costly to distribute and store. It will not require the cold chain storage and transport that the usual mRNA vaccine in frozen liquid form needs.

The phase three trials for ARCT-021, as the vaccine is called, will be conducted in three yet-to-be disclosed locations where the populations have yet to be vaccinated, Arcturus chief executive Joseph Payne told The Straits Times.

"It's going to be a phase three placebo-controlled trial involving approximately 15,000 people and multiple countries," he said.

"This trial needs to be conducted in an area where there's a high prevalence of Covid-19, and also in areas where it's easy to recruit for placebo-controlled trials, so that's in countries that do not have ready access to the first vaccines being rolled out."

In the ongoing phase two trials, conducted in Singapore and the US, both the single-dose and double-dose regimens were evaluated.

Most of the Covid-19 vaccines in use, such as the ones from Pfizer-BioNTech, Moderna, Oxford-AstraZeneca, Gamaleya, Sinovac and Sinopharm, require double doses. Only the Johnson & Johnson and CanSino vaccines are single-shot vaccines, which offer great convenience.

More than 354 million doses of various Covid-19 vaccines have been administered across 121 countries, according to data from Bloomberg.

A researcher at Arcturus Therapeutics working on a Covid-19 vaccine in San Diego, California, in March last year. The 5 microgram single-dose regimen will be a freeze-dried version easier to distribute and store. PHOTO: REUTERS

Many countries have recently received only their first batch of Covid-19 vaccines while others, mostly in Africa, have yet to receive them.

The Arcturus vaccine leverages the same RNA technology that Pfizer-BioNTech and Moderna use for their Covid-19 vaccines, which have been approved for use here.

This type of vaccine delivers instructions for building copies of the spike protein of the virus. These then help to trigger the immune system to produce antibodies. But, unlike the two mRNA vaccines already approved for use here, the ARCT-021 is a self-replicating vaccine.

The vaccine's co-developer, Professor Ooi Eng Eong from the emerging infectious diseases programme at Duke-NUS Medical School, explained that the ability of the ARCT-021 to replicate in the body simulates an actual viral infection.

Mr Payne said the vaccine candidate appears to be capable of producing a strong T cell response, so Arcturus is also looking to see if this is going to translate into higher efficacy or more durable efficacy.

T cells are immune cells that target and destroy virus-infected cells. Scientists think that T cells can help maintain durable immunity to the Covid-19 virus. They are hopeful that these T cells may be able to fight off Covid-19, even if antibodies show reduced effectiveness in the face of new variants.

Mr Payne also said that Arcturus is monitoring all the new variants but right now, there is no need to update its vaccine candidate because of the T cell protection it confers. "But if there's some variant that's nasty or very contagious or escapes our vaccine... then we can readily update it rapidly," he said.

Arcturus had said late last year that it was ready to ship out its vaccine in the first quarter of this year.

"We've completed some manufacturing efforts already this quarter and we're in a position to distribute them. But we don't have approval yet," said Mr Payne.

If phase three trials are successful, it can move on to get emergency use approval from authorities like the Health Sciences Authority in Singapore or the Food and Drug Administration in the US.

The target is to achieve emergency use approval for ARCT-021 in at least one jurisdiction or country in the second half of the year, he said.

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