

## Leading Covid-19 vaccine trial resumes in Japan but not US

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Trials on the coronavirus vaccine developed by AstraZeneca and Oxford University have resumed in Japan but not the United States, where the pharmaceutical giant is working with regulators, a statement released Friday said.

The Financial Times, citing sources close to the case, reported that the US drug regulator the FDA had expanded its investigation into the <u>serious side</u> <u>effects</u> suffered by one trial participant, which had led to a brief halt in the tests.

The British company did not respond immediately to an AFP request for comments.

"The Phase I/II clinical trial for the COVID-19 vaccine AZD1222 has resumed in Japan after discussion with the Japanese Pharmaceuticals and Medical Devices Agency," AstraZeneca said in a <u>press release</u> on Friday.

It said it had triggered a "voluntary pause to vaccination across all global trials on 6 September to allow review of safety data by an independent committee".

"Their recommendations have been supported by international regulators in the UK, Brazil, South Africa, India and now in Japan, who have deemed that the trials are safe to resume," the group said.

It will "continues to work with the Food and Drug Administration (FDA) to facilitate review of the information needed to make a decision regarding resumption of the US trial," added the statement.

Trials began at the end of August and group head Pascal Soriot said last month that the vaccine could still be ready by the end of the year, despite the setback.

The vaccine is one of the most advanced Western projects, having already been tested on tens of thousands of volunteers worldwide.

The World Health Organisation has identified 35 "candidate vaccines" being tested in human <u>clinical</u> <u>trials</u> around the world, with nine already in the final stage, or about to enter it.

The European Medicines Agency (EMA) estimates that it could take until at least early 2021 for a vaccine against COVID-19 to be approved and available for global use.

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