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China's Sinovac reports mixed findings in early coronavirus vaccine trials

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Sinovac Biotech, one of China's coronavirus vaccine front-runners, published mixed findings from its two first clinical trials Tuesday, raising the stakes in Indonesia, which has already declared plans to roll out Sinovac's vaccine.

While the vaccine appeared to be safe in these early clinical trials, the company reported that it generated lower levels of protective antibodies in the bloodstream compared with those arising in recovered coronavirus patients. In comparison, Moderna and Pfizer, which have separate experimental vaccines, had reported antibody levels on par with or higher than those produced in recovered coronavirus patients.

These early results put Sinovac on the back foot to prove its vaccine is effective in ongoing Phase 3 trials.

"That is a concern," said Thomas Campbell, associate dean for clinical research at the University of Colorado, of the low antibody levels in Sinovac's Phase 2 trial. "It's an important point here, in terms of comparing this vaccine to, for instance, the Moderna and

Pfizer vaccines."

Indonesia, the world's fourth-most populous country, recently made a big bet on Sinovac's vaccine as officials grapple with a severe coronavirus outbreak. In an interview with Reuters on Friday, President Joko Widodo said the government had sought emergency authorization from the country's food and drug agency to roll out the vaccine by the end of the year.

In its study published Tuesday in the peer-reviewed journal the Lancet, Sinovac wrote that despite the lower antibody levels, it believed its vaccine would prove effective. For other coronavirus strains, lower antibody levels have still conferred immunity, it said.

Whether this will be the case this time is being tested in Sinovac's Phase 3 trials underway in Indonesia, Brazil and Turkey.

After reporting strong antibody levels in Phase 2 trials, Moderna and Pfizer in recent days announced preliminary Phase 3 efficacy rates above 90 percent, a result greeted with enthusiasm from the medical world. (For their experimental coronavirus vaccines, Moderna is partnering with the National Institutes of Health and Pfizer is working with German biotechnology firm BioNTech.)

A Sinovac spokesman said Wednesday that the company could not immediately release its own preliminary Phase 3 efficacy rate, as not enough cases of the coronavirus have emerged yet in its study population.

"For Phase 3 preliminary analysis of results, we need to accumulate a certain number of cases for the data analysts to carry out their analysis," the Sinovac spokesman said in a statement to The Washington Post. "We don't have this data yet so we can't yet reply."

Campbell said Moderna and Pfizer were able to provide early Phase 3 results, in part, because of the escalating coronavirus outbreak in the United States, which has resulted in enough cases among those enrolled in their study for statistical analysis.

While Sinovac had announced a few results from its Phase 1 and Phase 2 trials over the summer, calling them a success, the peer-reviewed study this week was the first time it provided data and details.

Sinovac's Phase 1 trial began in April with 144 participants, and its Phase 2 trial began in May with 600 people. Participants ranged in age from 18 to 59 and were recruited from a single county of China's southern Jiangsu province.

In Sinovac's Phase 1 trial, 23 of the 96 who received vaccines reported side effects, which Sinovac said were mostly mild, such as pain at the site of injection. It said one person had a severe reaction of hives and recovered within three days with treatment.

In the Phase 2 trial, participants were quick to produce antibodies in response to the vaccine injection, but antibody levels remained below the measurements in recovered patients.

Liu Yang in Beijing contributed to this report.