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## Reliance Life Sciences seeks approval for Phase I trial of its Covid vaccine candidate



Reliance Life Sciences, part of India's largest private sector enterprise, has approached the drug regulator seeking approval to conduct clinical trials of its recombinant protein-based Covid-19 vaccine candidate.

The Subject Expert Committee (SEC), which advises the drug regulator on applications seeking approval for vaccines, new drugs and clinical trials, will review the application at a meeting on Thursday, people in the know told ET.

Reliance has approached the drug regulator seeking Phase I trial for its proposed two-dose vaccine, the same people said.

The aim of phase I clinical trials is to obtain reliable information on safety, tolerability, pharmacokinetics (PK), and mechanism of action of drugs with the objective of determining the maximum tolerated dose (MTD).

"Phase I trials are usually conducted for 58 days to check the tolerated dose strength. Once its done, the company can approach for Phase II/III trials," added the person.

Besides, the new vaccine candidate, the SEC to be conducted today will also review Bharat Biotech's data for its nasal vaccine of its Phase I trials.