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Covid-19 drug from S'pore-based firm to enter final trials soon

Lim Min Zhang

Trials for a potential treatment for Covid-19 are being accelerated, with the third and final phase for the drug due to start in a few weeks' time.

Developed by Singapore-based biotechnology company Tychan, the monoclonal antibody – or immune system protein – known as TY027 will be tested on 500 recently diagnosed Covid-19 patients.

The trial is expected to take a few months, but is the final step before the drug can be approved for treatment here.

Professor Ooi Eng Eong from Duke-NUS Medical School, who is one of the founders of Tychan, told The Straits Times yesterday that as a small company, Tychan does not have the resources to run trials with thousands of patients. But if the results are dramatic, there is a chance that fewer than 500 patients would suffice.

"We have to be tighter in how we recruit and the kind of patients that we enrol. The key criterion is for the patients to be in the first seven days of illness," he said.

"Limiting the kind of patients we can enrol would give ourselves the best chance of showing, in as short a time as possible and in as few patients as possible, that this drug works to prevent severe Covid-19."

Monoclonal antibodies are immune system proteins that are created in the laboratory, and can be specially designed and engineered to target Sars-CoV-2.

The advantage is that these antibodies can be developed over several months and produced in large batches. A single injection may last for a few weeks.

Half of the 500 patients will receive a placebo in the double-blind trial so that the drug's effectiveness can be tested, said Prof Ooi. Tychan will work with hospitals under SingHealth to recruit the patients.

The recruitment process has not started yet because the final trial is pending approval from the authorities.

Tychan will pay for tests and clinic visits beyond the standard medical care provided to the trial participants.

In the best-case scenario, TY027 could be approved as a drug treatment for Covid-19 by early next year, or even earlier, said Prof Ooi, who is deputy director of the Emerging Infectious Diseases Programme at Duke-NUS.

Clinical trials are commonly conducted in four phases, beginning with a small group to test the drug's safety and side effects, then moving on to larger groups to determine its efficacy.

Usually, in phase three, what is being tested is whether the drug works as intended in preventing disease or accelerating recovery.

TY027 is being explored for the treatment of Covid-19 patients in slowing the progression of the disease and speeding up recovery, as well as potentially providing temporary protection against infection.

A six-week phase one trial in June with 23 healthy volunteers yielded good outcomes in terms of safety, said Prof Ooi.

He added: "The safety profile has been excellent, there's minimal side effects... And the results have been very, very encouraging."

Commenting on the development, infectious diseases specialist Hsu Li Yang from the Saw Swee Hock School of Public Health said whether Tychan's drug would be effective will depend on clinical trial results, particularly in phase three.

"Currently, it's good that the drug is proven safe. An effective treatment, however, does not reduce the scale of an outbreak, although it will blunt the impact in terms of death and disability," he said, adding that the only effective treatment now for severe Covid-19 is dexamethasone, a steroid drug.

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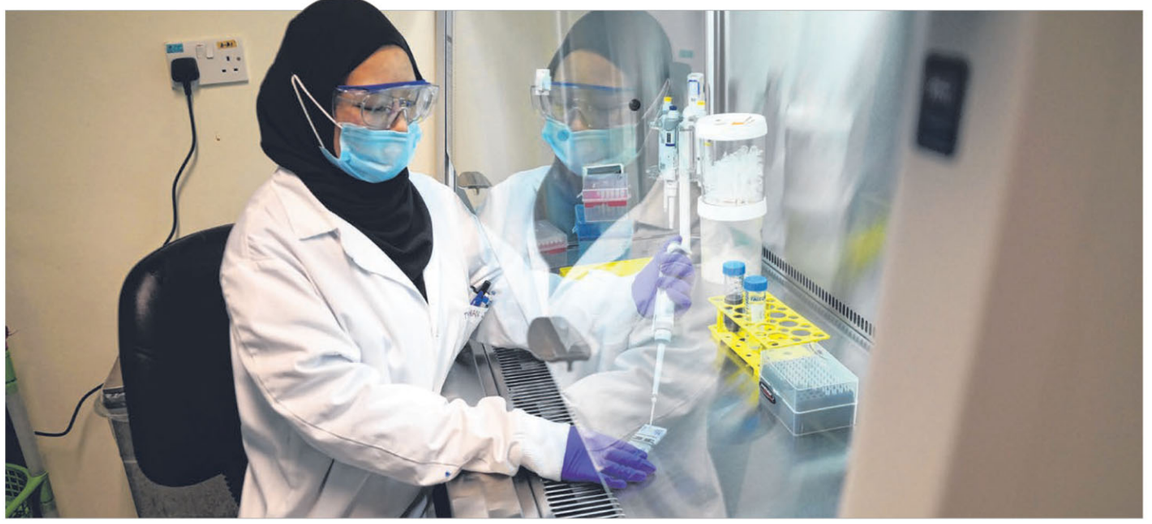
Finding a treatment

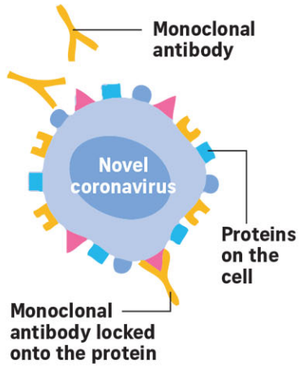
Singapore-based biotechnology company Tychan hopes to start the final trial for its monoclonal antibodies drug, TY027, in a few weeks. If successful, the treatment for Covid-19 could be approved by early next year.



PHASE THREE TRIAL

- **Sample size: 500 Covid-19 patients** diagnosed with the disease in the past seven days.
- **Could begin before the end of August**, depending on regulatory and ethics board approval.
- Patients taking part must provide informed consent. They could be from Singapore or the region
- Tychan will pay for tests and clinic visits that are outside of the standard of care.

HOW MONOCLONAL ANTIBODIES WORK



- Monoclonal antibodies, which are laboratory-produced immune system proteins, serve as substitute antibodies that mimic the human immune system's attack on infected cells, after they are injected into a patient's bloodstream.
- Antibodies are produced by the immune system after exposure to a foreign material invading the human body, such as a virus. They bind to different parts of the virus, helping to eliminate it from the body.
- Monoclonal antibodies have been used to treat other diseases, such as cancer and Alzheimer's disease.

Sources: TYCHAN, A*STAR, ASSOCIATE PROFESSOR HSU LI YANG, MAYO CLINIC PHOTO: TYCHAN STRAITS TIMES GRAPHICS