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Chinese Vaccine Maker in Talks With Countries on Early Approval

CanSino is in talks with several countries to secure emergency approval for an experimental coronavirus vaccine before large-scale safety and effectiveness trials are completed, according to a company executive.

By Saeed Shah

A Chinese pharmaceutical maker is in talks with several countries to get emergency approval to use an experimental Covid-19 vaccine, developed with the Chinese military, before the completion of large-scale safety and effectiveness trials, according to a senior executive at the company.

Early distribution by CanSino Biologics Inc. would give the company a head start over rivals by making its vaccine the first to go into public use internationally outside of clinical trials, although initial doses would likely be directed at health-care workers and others deemed essential, such as military personnel and police.

The effort shows the intensity of the race to become the first to develop a vaccine, though public-health experts say immunizing people widely before large-scale tests are completed could present serious health risks.

China's military has already approved the use of CanSino's vaccine before the completion of large-scale final testing, usually known as Phase 3 trials, according to a filing the company made with the Hong Kong stock exchange.

Pierre Morgon, senior vice president for international business at CanSino, said getting the vaccine out to millions of people now, before its clinical trials are complete, would broaden the base of knowledge about the drug's safety and effectiveness. By comparison, final-stage experimental trials typically involve several thousand participants. Such early distribution would require the countries to authorize the drug for emergency usage.

"It helps to build the safety database and certainly build the confidence in the fact that the vaccine is safe. If, in the meantime, if it is demonstrated as being effective in the Phase 3 trials, then it might be an accelerator for future contracts for vaccine supply," said Mr. Morgon.

The vaccine has been shown to promote an immune response, and no serious safety concerns have emerged in early human trials involving smaller groups, according to the company and trial results published in the *Lancet*, a prestigious international medical journal.

Mr. Morgon declined to name all of the countries the company is talking to, citing the discussions' confidentiality. He said they include Pakistan and countries in Latin America as well as some developed nations. So far, no countries have agreed to approve the drug on an emergency basis, Mr. Morgon said. The quest for a Covid-19 vaccine has turned into a fierce international competition, with national honor seen to be at stake, as well as lucrative contracts to supply the vaccine and the ability to get economies motoring again for those countries with access to the immunization.

Russia alarmed health professionals and regulators around the globe this month by saying it had become the first country to register a Covid-19 vaccine, even though it hadn't completed trials or published test results in a reputed scientific journal.

Vaccine developers across the world are rushing to finish trials before the end of the year. Negotiating deals for emergency-use authorization would allow CanSino to leapfrog others in the race.

But vaccines, intended for large numbers of healthy people who don't have the disease, are virtually never approved for widespread use before the completion of large-scale trials.

“It's breaking all the global conventions around science and ethics. It's a huge gamble,” Lawrence Gostin, professor of global health law at Georgetown University, said of any country authorizing emergency use of a vaccine before it completes tests.

Most medications that pass early phases of testing for safety and effectiveness—as CanSino's vaccine has—don't succeed in the larger final-stage trials, he said.

“You might end up rolling out a vaccine that causes enormous hazards in the population or is ineffective. If it's ineffective, then the public is going to assume they're immune and go about their business and spread Covid[-19] like mad,” said Prof. Gostin.

The Trump administration, despite criticism, has approved the emergency use of some drugs and therapies to treat Covid-19. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, warned in recent days against emergency use of a Covid-19 vaccine.

Dr. Fauci has also indicated that the U.S. is unlikely to use a Chinese or Russian vaccine because of doubts over testing procedures. Instead, the U.S. has spent billions of dollars paying for some potential vaccines to be manufactured in advance of completing tests, but only for distribution after successful trial results come in.

A senior Pakistani official confirmed that emergency use of the CanSino vaccine was discussed with the company and among a domestic expert committee. The official said that such an option is being kept under consideration but that it wasn't presently necessary, as coronavirus cases and deaths have declined sharply over the last couple of months. Nevertheless, Pakistani officials fear that the disease could come roaring back in the winter.

Even if multiple vaccines are successfully developed, there will be a severe shortage until at least 2022, experts say, because there isn't manufacturing capacity available to make enough for the whole world's population.

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CanSino is about to enter final-phase trials in Russia, Pakistan and Saudi Arabia, according to officials in those countries. CanSino is also in talks for trials with Brazil and Mexico, according to Chinese state media.

Petrovax, CanSino's local partner in Russia, said it wasn't aware of the Chinese company approaching the Russian government for emergency-use authorization.

A Brazilian health ministry official said that it would make available a vaccine of proven effectiveness to the country's population as soon as it has access to one, but declined to comment on whether it is talking with CanSino.

Officials in Saudi Arabia and Mexico didn't immediately respond to requests for comment.

Three of the six vaccines already in final trials globally are Chinese. Trials are separate from emergency-use authorization, but the two could potentially run in parallel in some countries.

China has been especially proactive in rolling out CanSino's vaccine candidate. It was the first that authorities approved for human clinical trials in March. Earlier this month, China's intellectual property regulator granted the country's first Covid-19 vaccine patent to the CanSino vaccine.

Countries that have expressed interest in early emergency use of the vaccine intend it for critical workers such as health-care personnel, vulnerable groups and people deemed essential for the proper functioning of the state, Mr. Morgon said.

In some countries, that list could also include armies and police forces.

A large country might be able to buy one to two million doses from CanSino under the plan, said Mr. Morgon.

CanSino has developed its vaccine jointly with the Chinese Military Academy of Medical Science. Mr. Morgon said the vaccine had already been given to thousands of soldiers.

Chao Deng, Thomas Grove and Georgi Kantchev contributed to this article.

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