

CORONAVIRUS

“None of us were ready” to manufacture genetic vaccines for a billion people

The CEO of Moderna, whose novel covid vaccine could be authorized this week, is worried about how to make enough of the product.

By Antonio Regalado

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ALEX KRAUS/BLOOMBERG

The first covid-19 vaccine developed as part of Operation Warp Speed is likely to be authorized for emergency use this week in the US following an all-day meeting of federal medical advisors today, December 17.

The shot, called mRNA-1273, was developed by the biotech company Moderna, and the US is relying heavily on it to meet the US government’s timeline of vaccinating most of the population by June.

The vaccine, which contains a snippet of the coronavirus's genetic code, is based on a novel approach that employs an injection of messenger RNA encased in fatty particles. A similar vaccine, developed by Pfizer and BioNTech, was authorized last week, but the US secured only 100 million doses. Supplies are limited as the world clamors for the shot.

While Pfizer worked independently, Moderna received billions in funding from the US and collaborated closely with the National Institute of Allergy and Infectious Diseases, making its vaccine the first success of Operation Warp Speed, the administration's moonshot program to end the pandemic.

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In a large clinical trial run in the US, the Moderna shot worked exceptionally well, besting all expectations. After two doses, the efficacy against covid-19 was 94%. A few people who got the vaccine in the trial still got infected, but none developed a severe case of covid-19.

MIT Technology Review spoke with Moderna CEO Stéphane Bancel earlier this week about his frame of mind as his company's product nears authorization.

The US is depending heavily on Moderna's shot to restore the economy and day-to-day life. On December 14, the Trump administration exercised an option to buy an additional 100 million doses, bringing the total that Moderna has promised to 200 million. So far, however, there is only enough made to vaccinate a few million people.

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TR: What were you thinking when you woke up this morning?

Bancel: I am an early riser and I went to do some sports. I was thinking mostly about manufacturing and how we scale manufacturing. As the CEO I am always thinking about the next game, and the next game is manufacturing. This is a big week at the FDA. But I am not worried about the EUA [emergency-use authorization], because the data is the data. I am worried about making more product.

When did you first believe this vaccine was going to work?

I thought so back in May, when we saw very high levels of neutralizing antibodies in all the early trial participants. We knew from animal experiments that the antibodies are the best indicator of future efficacy.

The vaccine works great—but it's disappointing there isn't enough for everyone, in the US or in the world. Why is that?

This was anticipated all along. There was never going to be enough of any one vaccine for the planet. What is remarkable is that 11 months since the DNA sequence of the virus became available, you will have two approved mRNA vaccines, which has never happened before with any technology. That is amazing, but this has never been a commercial technology before. No one has a factory sitting idle able to make 1 or 2 billion doses a year.

What is the bottleneck? Is it the raw materials or the equipment?

At the end of the day, it's a new technology. Imagine the people making cars in the 1920s. If someone had said "I want a billion cars," the answer would have been "What are you talking about?" None of us were ready because no mRNA vaccines have been approved before, but now we are building the infrastructure to make a billion doses.

Anthony Fauci, the director of the National Institute of Allergy and Infectious Diseases, said last week that this vaccine was "developed" by the NIH. That it's their invention. What do you think of that?

The vaccine technology was developed by Moderna. What we have done for a period of time is to send them products to try with different viruses. In this case, for the mRNA design, we had two teams working in parallel, to increase the chances. When the coronavirus sequence was put online in January, we had a meeting with them 48 hours later. And both teams, NIH and Moderna, had come to the same design.

What is the next disease or infection for this technology to conquer after covid-19?

Already, before covid, we were working on CMV [cytomegalovirus], which is the number one cause of birth defects in the US. We have beautiful phase 2 data from September, and we will be in phase 3 next year. We think every woman will get this vaccine before getting pregnant. And after that the comes the flu. The flu vaccine efficacy is pretty bad, just 40 or 50%.

Throughout your company's history, you've been searching for how to apply this technology. Do you think vaccines will remain the killer application?

We always said it is was about developing the right delivery technology. And this is something that takes years, not two weeks. We have some intriguing data, published in September, in head and neck cancer. In cardiology, we see the ability to increase blood flow in a human. We think it's going to be important, and we believe over time it's going to be applied to a broad range of diseases. We think there are 10 or 20 different cell types to which we can deliver mRNA. It's by organ system, and it's by cell type. One you have the delivery, then you can do lots of different drugs, because RNA is information. **T**

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