GlobalResearch
Center for Research on Globalization

It Could Be Several Years for 2 Leading COVID-19 Vaccines to Debut, Wall Street Analysts

By Arlene Weintraub
Global Research, April 22, 2020
FiercePharma 17 April 2020

Region: USA
Theme: Intelligence, Science and Medicine

Ever since President Donald Trump said last month that a COVID-19 vaccine could be ready in 12 to 18 months, Wall Street analysts have been warning that the real timeline is likely to be longer, even though more than 40 candidates are in development. But just how much longer will it take to bring a vaccine to market?

Global analytics firm Clarivate took a look at vaccines from two companies that have entered clinical trials—Moderna and Inovio—and came to a sobering conclusion: It will take at least five years for either vaccine candidate to complete the development process through full regulatory approval. And neither company has a high probability of success, Clarivate told FiercePharma.

If the FDA granted the companies emergency authorizations—as it did for the malaria drugs chloroquine and hydroxychloroquine recently, without proof they could effectively treat COVID-19—that could cut the timeline short. But as SBV Leerink analysts recently pointed out, regulators tend to eye vaccine safety very closely, which is one reason why R&D timelines are longer for those products compared with drugs.

Using a tool it developed called Cortellis Analytics, Clarivate estimated that Moderna has just a 5% probability of success with its COVID-19 vaccine mRNA-1273, and that the time window for approval would be 5.2 years. The low probability of success reflects the fact that mRNA is a new, unproven approach to vaccines, said Sarah Hardison, Ph.D., head of product, regulatory and pharmacovigilance at Clarivate, in an email.

Granted, Moderna has garnered plenty of support for mRNA-1273—not the least of which was yesterday's $483 million grant from the Biomedical Advanced Research and Development Authority (BARDA) to accelerate late-stage trials and manufacturing. Furthermore, Moderna has vowed to start a phase 2 study in the second quarter and could start a phase 3 as early as this fall.

If Moderna makes good on those promises, the ultra-fast timeline "would be unprecedented and [would] certainly make an impact on our predictions," Hardison said.

A spokesperson for Moderna did not immediately respond to a request for comment from FiercePharma, but during a conference call with analysts Friday morning, chief medical officer Tal Zaks, M.D., Ph.D., said that "our responsibility is to demonstrate the clinical benefits, derisk the safety database….as fast and as diligently as humanly possible."

When asked if Moderna might get an emergency-use approval from the FDA to get

mRNA-1273 on the market quickly, Zaks said he couldn't make any promises. "The decision on emergency use is going to be an evolving one…as the data matures to make that determination," he said. "So it's very hard to predict today."

Clarivate's Cortellis tool uses machine learning to forecast development timelines and the probability of success for drug candidates that have entered clinical trials. The firm said in a recent online post that as of April 8 there are 185 companies and research institutes working on 156 COVID-19 medicines and vaccines, 11% of which are in clinical development.

The other vaccine candidate that Clarivate evaluated was Inovio's DNA vaccine INO-4800, which the company moved into clinical testing last week. Clarivate forecasts a probability of success of 15% for INO-4800 and an approval timeline of 5.5 years.

A spokesperson for Inovio said in a statement emailed to FiercePharma that the company does not comment on speculative or theoretical scenarios. "Based on our intimate knowledge of and extensive experience with our proprietary DNA platform, including developing vaccine candidates against related coronaviruses, we remain highly confident in the viability and likelihood of success of our vaccine candidate for the novel coronavirus," the company said.

Clarivate isn't the only firm raising questions about the growing optimism that a solution to COVID-19 will rescue everyone from their quarantines soon. Analysts at SVB Leerink spoke to a vaccine development-specialist earlier this month and warned in a report to investors that "safety is often more important than efficacy to regulators, and long-term safety must be established before" a vaccine will be approved.

One prediction that most analysts have agreed on is that effective drugs to treat COVID-19 will likely hit the market before any vaccines do. Clarivate forecasts an 89% chance of success for Gilead's remdesivir, which is in phase 3 trials and is widely considered to be the leading candidate. Clarivate has estimated the drug could be approved to treat COVID-19 in 2022.

Waiting two years for a drug that seems to be urgently needed now—not to mention five years for a vaccine—may seem unreasonable given the increasingly loud calls for quick solutions to COVID-19. Clarivate's Hardison says support such as BARDA's investment in Moderna's vaccine candidate could change how the Cortellis algorithm makes its forecasts, which could ultimately result in a more optimistic timeline.

"This is an unprecedented and fast-changing environment," Hardison said, "with increased investment, shortened timelines, and unpredictable FDA [and] regulatory authority responses."

*

Note to readers: please click the share buttons above or below. Forward this article to your email lists. Crosspost on your blog site, internet forums. etc.

Featured image is from Pixabay

The original source of this article is FiercePharma

Articles by: Arlene Weintraub