Where are we with COVID-19 vaccine?

Introduction

Worldwide researchers are racing to develop a vaccine against SARS-CoV-2, the virus that causes COVID-19, which has brought the world to a social and economic standstill. Hundreds of institutions and individuals in academic, biotechnology, government, and pharmaceuticals - embarked on one of the most consequential scientific endeavors in living memory.

Here are few facts about vaccine development:

1. Vaccine developers and government officials are publicly reporting timelines for emergency use of vaccine candidates between the 4th quarter of 2020 and the 1st quarter of 2021.
2. The early data on vaccine safety and immunogenicity in Phase I and II trials are promising—although in a limited number of subjects to date.
3. The discrete characteristics of the virus, the sheer number of development efforts, and innovators' unprecedented access to funding all provide reasons to believe that a COVID-19 vaccine can be developed faster than any other vaccine in history. (It took four years to develop the mumps vaccine, which was previously the fastest developed novel vaccine.[1]) More than 50 candidates are expected to enter human trials in 2020, and 250 total vaccine candidates are being pursued. Historical attrition rates would suggest that such a pipeline could yield more than seven approved products over the next few years.
4. Vaccine manufacturers have announced cumulative capacity that could produce as many as one billion doses by the end of 2020 and nine billion doses by the end of 2021.

Taken together, all the evidence suggests that COVID-19 vaccines are likely to become available for focused populations somewhere around the first quarter of 2021.

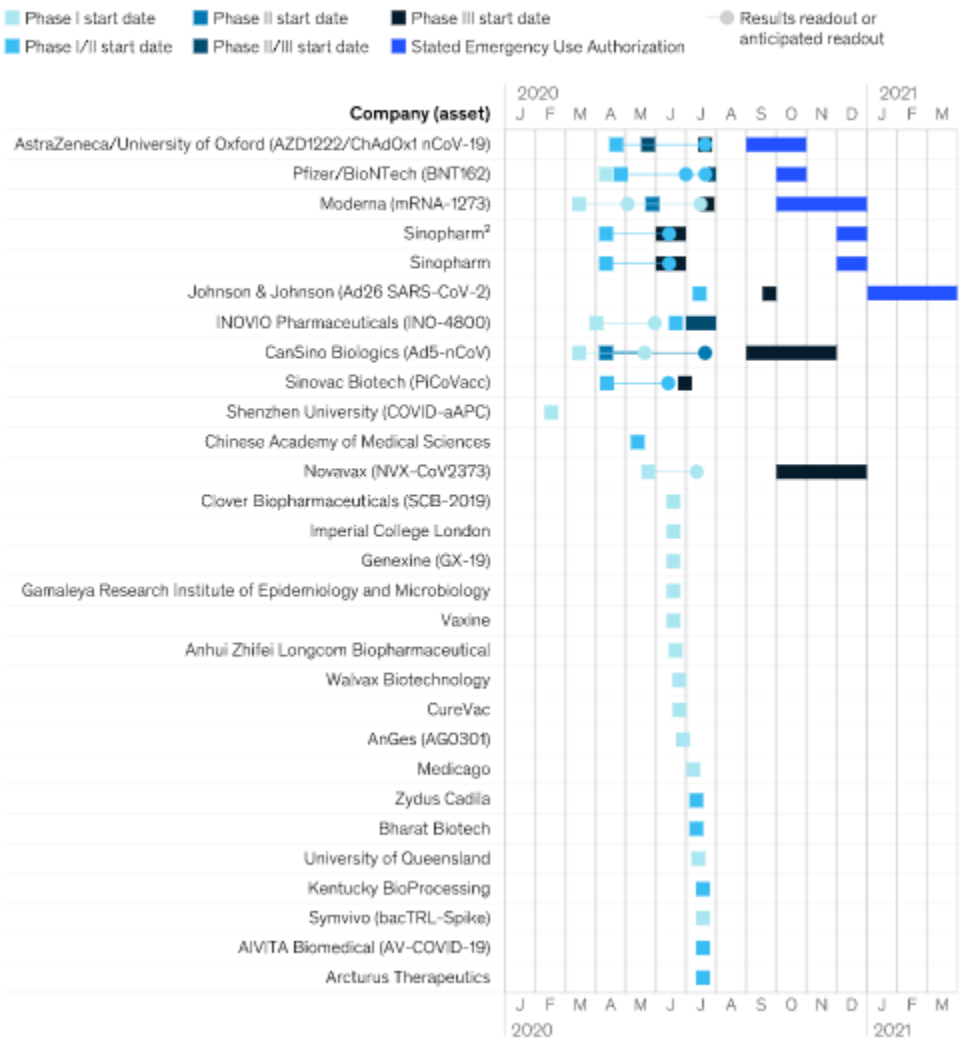
A question of timing: Will we have a vaccine, and if so, when?

Given the sheer number of potential COVID-19 vaccines in development and the public statements from several developers, it seems likely that one will be available in the United States between the fourth quarter of 2020 and the first quarter of 2021, with more following throughout the year—potentially granted under the FDA's EUA guidelines.[2]

Similar approvals are being sought by companies in China and Europe: at least five large vaccine developers have announced that they intend to submit applications for EUA, or the local equivalent, for their candidates before the end of 2020 (Table 1).

A review of the COVID-19 vaccines pipeline reveals robust development efforts.

Announced clinical-trial timelines for COVID-19-vaccine candidates[1]



Source: Biocentury; Clinical trials.gov; Milken Institute Covid- 19 Treatment and vaccine tracker; press search

Several companies have released data from Phase I and Phase II clinical trials that are promising:

- In June, Sinovac Biotech released preliminary results from a Phase I/II trial of its candidate, citing the induction of neutralizing antibodies in more than 90 percent of people who were tested 14 days after receiving two injections two weeks apart, with no severe adverse events reported.[3] China National Pharmaceutical (known as Sinopharm) presented interim readouts from a Phase I/II trial of its candidate in the same month, claiming that 100 percent of participants who received two doses over 28 days developed neutralizing antibodies.[4]

- In early July, Pfizer and BioNTech published preliminary results from a Phase I clinical trial of their candidate, indicating that "geometric mean neutralizing titers reached 1.8- to 2.8-fold that of a panel of COVID-19 convalescent human sera."[5] In that same time frame, Moderna published interim data from a Phase I trial of its vaccine candidate, demonstrating that 41 of 41 vaccinated participants developed neutralizing antibody titers using both a live virus and a pseudovirus assay. Across dose levels, titers were either comparable to or above those seen in a panel of convalescent sera. The geometric mean titers post-boost at the 100 microgram dose were between 2.1- and 4.1-fold higher than those seen in convalescent sera.[6]

- In November, Pfizer and BioNTech announced vaccine candidate were found to be more than 90% effective in preventing COVID-19 in participants without evidence of prior SARS-CoV-2 infection in the first interim efficacy analysis. Study enrolled 43,538 participants, with 42% having diverse backgrounds, and no serious safety concerns have been observed; Safety and additional efficacy data continue to be collected. Clinical trial to continue through to final analysis at 164 confirmed cases in order to collect further data and characterize the vaccine candidate's performance against other study endpoints.[7]

Vaccine Development in India

- In November, Bharat Biotech announced India's first indigenous Covid-19 vaccine candidate, Covaxin. The vaccine has already been evaluated in 1000 subjects in phase I and phase II clinical trials and has shown promising safety and immunogenicity data. The trial will involve 25,000 volunteers over 18 years of age across 25 centres in the country and is taken up in partnership with Indian Council of Medical Research (ICMR). [8]

Summary

The timing question is becoming a bit clearer, as is the question of how much value may be created by the global launch of successful vaccines against COVID-19. Based on the established set of facts, experts agree a vaccine for COVID-19 is likely to be available somewhere between the fourth quarter of 2020 and first quarter of 2021, most likely for use in specific populations, with additional candidates coming on line by the end of 2021.

References

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