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Editorial

Hot race for COVID-19 vaccines – Light at the end of the tunnel just got brighter

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INTRODUCTION

While the COVID-19 pandemic continues to gallop across the world, there is plausible hope that the pandemic might be dead soon – thanks to rapid emergence of positive data from various ongoing clinical trials involving COVID-19 vaccine candidates.[1] With UK regulatory authorities having just provided emergency approval for the use of the Pfizer vaccine, the race is heating up among the 187 potential vaccine candidates (as per WHO), 44 of which are in advanced human clinical studies.[2,3]

Besides efficacy, a key deciding factor will be safety. We are aware that all vaccines have some adverse reactions – from data generated among millions of recipients. While they may occur in as many as half of the individuals, majority are mild and transient and do not require any pharmacological intervention. Common reactions include local injection site issues (such as pain, itching, redness, and swelling) as well as systemic symptoms (such as bodyache, muscle stiffness, soreness, headache, nausea, and vomiting). Many a times, more significant reactions have been reported, but their relationship to the vaccine has been rarely proven.

PROMISING COVID-19 VACCINE CANDIDATES

For this article, we shall discuss six of the most promising vaccines whose data are publicly available [Table 1].

1. Our very own Bharat Biotech's COVID-19 vaccine is in phase 3 at 24 Indian centers. Their plan is to evaluate 25,800 individuals. This is an inactivated vaccine that is a product of the National Institute of Virology, Pune. It is from an Indian strain of COVID-19 isolated by them.[4]

Phase 1 of this COVAXIN trial commenced in August 2020. In the early stage of the trial, a 35-year-old volunteer from Nagpur developed pneumonitis after receiving the study medication. The Central Drugs Standard Control Organization (CDSCO) did an evaluation and concluded that the adverse reaction was not related to the vaccine. He recovered from the incidence without any sequelae.

Bharat Biotech continued its vaccine development without further safety flags. It now holds a place of pride as the first vaccine developed in India to have entered Phase 3 clinical trials. The first volunteer to receive a dose of this vaccine is from the prestigious All India Institute of Medical Sciences, New Delhi. When successful, it will be a proud moment for the Make in India.

Table 1: Comparison of key features of most promising COVID-19 vaccine candidates.

Description	1	2	3	4	5	6
Name	BBV152 (Covaxin)	ChAdOx1nCov19 (AZD1222)	Sputnik V	Ad26Cov2S	mRNA-1273	BNT162b2
Type	Inactivated vaccine from an Indian strain of COVID-19 isolated by NIV	Adenovirus	Adenovirus	Adenovirus	mRNA	mRNA
Company	Bharat Biotech	University of Oxford/Astra Zeneca	Gamaleya National Research Center	Jannsen (J and J)	Moderna	Pfizer-BioNTech
Country of origin	India	UK	Russia	USA	USA	USA
Indian partner	ICMR and NIV, India	Serum Institute of India	Dr. Reddy's and Hetero, India	NA	NA	NA
Doses	2 doses	2 doses	2 doses	1 dose	2 doses	2 doses
Interval between doses	28 days	30 days	21 days	NA	29 days	21 days

ICMR: Indian council of medical research, NIV: National institute of virology. All these vaccines are administered as an intramuscular injection

2. Astra Zeneca's vaccine has been developed in collaboration with Oxford University, UK. Their plan was to study its effects in 30,000 individuals. The trial was temporarily put on hold when one of the participants developed transverse myelitis. Indian Council of Medical Research and Drugs Controller General of India (DCGI) evaluated the data and concluded that this adverse reaction was not caused by their vaccine. As a result the trial continued.

Unfortunately, that was not the only problem with this vaccine. New information has become available that the overall efficacy is 62% in some patients. If this is true, it becomes a significant data integrity and quality question mark. The other controversy is regarding actual recommended first dose – full or half of the second dose. The CDSCO's Subject Expert Committee on COVID-19 had, in its meeting on December 01 2020, decided to ask Serum Institute of India (SII) to revise its protocol for the Phase 2 and 3 clinical trials, the revised protocol having been submitted by SII on December 02 itself. SII is likely to be ready with its application to DCGI for emergency use license in a few weeks.[5]

3. Sputnik V, from Russia, was granted regulatory license as early as August 11, 2020. Its trial subjects include those from India, Russia, UAE, Hungary, Armenia, Belarus, and Venezuela. Russia is allowing Hetero to manufacture 100 million doses in India and data from its phase three trial conducted in India by Dr Reddy will be available for submission to DCGI by March 2021. Russia has announced that their vaccine will be available to the international community at the price of about USD 10 – which could be significantly lower than its competitors. This could be a great boon for individuals, health authorities, and the economy of many countries.[6]
4. Janssen's vaccine candidate is being evaluated in 60,000 subjects from Brazil, Chile, Columbia, USA, Mexico, Philippines, Peru, and South Africa.[7]

The biggest advantage of this vaccine could be that it is required to be administered only once (single dose). It was halted after a patient developed as serious adverse event. After thorough evaluation by the regulatory authorities, it was decided that the relationship of the SAE to the vaccine could not be established. Hence, the Phase 3 trial was given permission in October to restart.

5. Moderna vaccine began its human trials in USA.[8] How a company that was incorporated recently, never had produced a vaccine before and was able to quickly standardize vaccine production with the largely untested mRNA method which is an enigma. So also is the question of how it was able to raise funding from National Institutes of Health (NIH), USA. Their Phase 3 COVE study enrolled more than 30,000 participants in the U.S. and is being conducted in collaboration with the National Institute of Allergy and Infectious Diseases, part of the NIH, and the Biomedical Advanced Research and Development Authority. Primary efficacy analysis data showed that COVID-19 infection occurred in 196 cases of which 30 cases were severe. Their reported vaccine efficacy is 94.1% (100% for severe COVID-19) with good safety data across 2 months medial follow-up as required by U.S. Food and Drug Administration (U.S. FDA) for Emergency Use Authorization (EUA). The company will apply to U.S. FDA and European Union authorities in the immediate future. If regulatory approval is received, Moderna is in a position to make the vaccine available this month itself.
6. Pfizer's vaccine was conducted in 150 centers from USA, Turkey, South Africa, Argentina, Brazil, and Turkey.[9] Data demonstrated that the vaccine was well tolerated across all populations with over 43,661 participants

enrolled; no serious safety concerns were observed; the only Grade 3 adverse event >2% in frequency was fatigue at 3.8% and headache at 2.0%. Safety data also achieved milestones required by U.S. FDA for EUA. Thanks to this, it is the first vaccine from the western world to receive regulatory approval (from UK) – on December 2, 2020. The companies previously signed an agreement to supply a total of 40 million doses to the U.K. with delivery in 2020–2021.The company awaits approval in USA (meeting scheduled in the 2nd week of December 2020).

CONCLUSION

The light at the end of the COVID-19 pandemic tunnel seems to be brightening. The next 6 months shall decide the fate of many across the globe. We must remind ourselves that vaccine studies can look at primary end points of reducing infection, disease, and/or transmission. The final proof of the pudding shall be efficacy in reducing or preventing severe disease or death – a difficult endpoint that is unlikely to be assessable in Phase 3 clinical trials. In the meantime, we live on hope, continue to take optimal precautions and look forward to being vaccinated safely and quickly.

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