

Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 200th meeting held on 04.01.2022 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/CT/21/000163 COVAXIN & ChAd36-SARS-CoV-2-S Corona Virus Nasal Vaccine, [BBV154] [Phase III clinical trial]	M/s. Bharat Biotech International Ltd.Hyderabad	<p>The firm presented its proposal for grant of permission to conduct Phase III clinical trial for administration of BBV154 as heterologus booster (third) dose for the subjects who were administered COVAXIN & COVISHIELD as primary vaccines.</p> <p>The firm has also presented the interim data from following clinical trials:</p> <ol style="list-style-type: none"> i. Immunogenicity data of 190 subjects including Nab titres of Phase II clinical trial of BBV152 (COVAXIN) wherein booster (third) dose administered 6 months after second dose of BBV152 (COVAXIN). ii. Safety & Immunogenicity data of 608 subjects of Phase II Heterologus prime boost trial of BBV152 (COVAXIN) & ChAd36-SARS-CoV-2-S Corona Virus Nasal Vaccine, [BBV154]. iii. Safety & Immunogenicity data of 200 subjects of Phase II trial of ChAd36-SARS-CoV-2-S Corona Virus Nasal Vaccine, [BBV154]. <p>Based on above, the firm requested for grant of permission to conduct Phase III clinical trial of BBV154 for the standalone indication as a booster dose.</p> <p>The committee noted that the vaccine is yet to be approved for emergency or otherwise situation for primary vaccination in reply to which the firm proposed to carry out Phase III trial with active comparator for considering the vaccine for approval and also proposed to conduct the Phase III clinical trial with five arms for its indication to use as a booster dose to the approved vaccines in India.</p> <p>Subsequently, after taking sometime, firm came-out with the preliminary concept and presented their plan that it will carry out a Phase III superiority trial with COVAXIN as active comparator in 3000 subjects out of which the immunogenicity cohort comprises of</p>

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			<p>1000 subjects.</p> <p>Further, the firm also presented the revised design of Booster dose study comprising of five arms with COVAXIN or BBV154 as a booster for subjects who had COVAXIN or COVISHIELD as primary vaccination.</p> <p>After detailed deliberation, the committee in principle agreed for conduct of both, Phase III superiority study & Phase III booster dose study in parallel in the light of pandemic situation and the potential in-vitro data shown by the firm against the omicron with the proposal to the firm that the superiority trial data results to be made available and analysed by the firm for taking into account the results from the nasal formulation booster trial data.</p> <p>Accordingly, the firm should submit the protocol(s) as recommended for approval.</p>
2.	<p>[BIO/IMP/21/000056]</p> <p>Recombinant Human adenovirus serotype 26 (rAd26) COVID-19 vaccine [SPUTNIK-Light]</p>	<p>M/s. Dr. Reddy's Laboratories, Ltd. Hyderabad</p>	<p>In light of the recommendations of the SEC (COVID-19) in meeting dated 27.12.2021, the firm submitted updated clinical trial data from Phase III clinical trial of Recombinant Human adenovirus serotype 26 (rAd26) COVID-19 vaccine conducted in India.</p> <p>The firm also presented comparative immunogenicity data between seronegative and seropositive subjects at baseline.</p> <p>The committee noted that the efficacy data from Phase III clinical trial in Russia is available in 57 target cases on the basis of which interim analysis was performed by the firm and informed that further interim analysis will follow as the data is available.</p> <p>Further, firm has also shown the 42 days immunogenicity data in India, and the effect of Sputnik-Light as booster after Sputnik-V vaccination to tackle the Omicron, based on which firm proposed to seek approval in future for Sputnik-Light as booster to Sputnik-V.</p> <p>After detailed deliberation, the committee recommended that firm should submit:</p> <ol style="list-style-type: none"> i. Efficacy data from Russian Phase III clinical trial after unblinding.

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			<p>ii. Updated data of SARS-CoV-2 glycoprotein antibodies & neutralising antibodies at Day 90 in Phase III Indian study.</p> <p>iii. Virus neutralization data of standalone Sputnik Light vaccine against Omicron variant.</p> <p>iv. And the proposal for their request to consider Sputnik-Light as booster to Sputnik-V for evaluation alongwith above data as appropriate.</p> <p>Accordingly, firm should submit above data and proposal for further evaluation by the committee.</p>
3.	BIO/CT/21/000145 Olokizumab	M/s. DRL	<p>In-light of the recommendations of the SEC dated 02/11/2021 the firm presented the amendments in the Phase-III clinical trial protocol.</p> <p>After detailed deliberation the committee recommended for grant of permission to conduct the Phase-III clinical trial subject to following modifications in the proposed study protocol –</p> <ol style="list-style-type: none"> 1. Inclusion criteria should be as per innovator’s clinical study design conducted in Russia. 2. Study endpoints (specifically 29 days mortality) and rescue treatments shall be as proposed. 3. Power of the study design shall be revised to 90%. 4. Interim analysis may be carried out after reaching 50% of the target sample size. <p>Accordingly, firm should submit revised protocol to this office for consideration and approval.</p>
4.	BIO/CT/20/000093(Part-I) Itolizumab	M/s. Biocon Biologics Limited	<p>The firm presented the clinical study report for Phase IV study conducted in 300 subjects with Itolizumab alongwith their earlier studies in India with a request to regularize the indication for COVID-19.</p> <p>Further, the firm also informed that a comparative trial to assess the safety and efficacy of Itolizumab as approved by CDSCO is already being undertaken, results of which</p>

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			<p>are awaited.</p> <p>After detailed deliberation, the committee recommended for the continued marketing of the said drug under the restricted use in emergency situation and sought for the data from the comparator trial under progress and any other publications, foreign country approval, for consideration of regularization of the indication.</p>