

Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 185th meeting held on 23.09.2021 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/CT/21/000134 Novel Corona Virus-2019-nCov vaccine (Recombinant) [3mg, two dose schedule]	M/s Cadila Healthcare Ltd.	In light of earlier recommendation dated 16.09.2021, the firm presented revised clinical trial protocol for conduct of Phase III clinical trial of Novel Corona Virus-2019-nCov vaccine (Recombinant) 3mg in two dose schedule before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial subject to condition that, volume of blood to be withdrawn in the pediatric cohort shall be as per National Ethical Guidelines for Biomedical and Health Research Involving Human Participants issued by ICMR.
2.	BIO/CT/20/000186 SARS-CoV-2rS Protein Nanoparticle Vaccine Phase II/III clinical trial.	M/s Serum Institute of India Pvt. Ltd.	The firm presented safety data of initial 100 participants of 12-17 Years of Age - 7 Days Follow-up after first dose of SARS-CoV-2 rS vaccine with Matrix-M1 adjuvant along with the DSMB recommendations before the committee. After detailed deliberation, the committee recommended for allowing enrolment of subjects of 7 to 11 years of age group as per the protocol and the firm should submit the safety data of the first 100 participants before proceeding to further participants of lower age group.
GCT Division			
3.	CT/86/21 FP-025	M/s. Medpace	The firm presented the proposal for Phase 2/3 clinical trial before the committee. Assessment of risk vs. Benefit to the patients: The safety profile of the study drugs from preclinical toxicology studies including repeat dose toxicity & Phase-I clinical study justify the conduct of the trial. Innovation vis-à-vis Existing Therapeutic option: The purpose of the study To evaluate

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
			<p>the efficacy of FP-025, compared to placebo, in adult patients with severe to critical COVID-19 with associated ARDS, when used with standard of care treatment for COVID-19</p> <p>Unmet Medical need in the country: The test drug may potentially provide treatment in patients with severe to critical COVID-19 with Associated Acute Respiratory Distress Syndrome</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the study, subject to following conditions:</p> <ol style="list-style-type: none"> 1. Study sites should be geographically distributed across the Country. 2. Sample size should not be more than 25 from India. 3. The firm should submit results of Phase – II part of the study for review by committee before initiation of Phase-III part of study.
4.	CT/98/21 MRG-001	M/s. Navitas	<p>In light of earlier recommendation dated 02.09.2021, the firm present their justification for conduct of the Phase IIa study before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the study as presented.</p>
SND Division			
5.	SND/CT/20/000021 Niclosamide IM depot Injection 960 mg/4ml	M/s Daewoong Pharma	<p>The firm presented their proposal for major changes in Phase I Clinical Trial protocol of Niclosamide IM Depot injection before the committee.</p> <p>After detailed deliberation, the committee recommended for approval of the amendments as presented.</p>