Recommendations of the SECmeeting to examine COVID-19 related proposalunder accelerated approval process made in its 190th meeting held on 26.10.2021at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
GCT Division			
1.	CT/77/21 Proxalutamide(GT0918)	M/s. CBCC	In light of earlier recommendation dated 22.07.2021, the firm presented their safety data for proposed Phase III clinical trial before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study subject to the following conditions: 1. No of patients to be recruited should not exceed 200. 2. Patients from India inclusion criteria should be as per GOI/ICMR guidelines for mild COVID patients.
2.	CT/84/21 Itolizumab	M/s. Biocon Limited	In light of earlier recommendation dated 26.08.2021& 27.08.2021, the firm presented their proposal for Phase III clinical trial before the committee. After detailed deliberation the committee recommended for grant of permission to conduct the study as per protocol presented.
3.	CT/126/21 INO-4800	M/s. Bioagile	The firm presented their Phase II/III clinical trial proposal before the committee. **Assessment of Risk versus benefit to the patients-**The safety profile of the study drug from preclinical and clinical studies justify the conduct of the trial. **Innovation vis-a-vis existing therapeutic-** To evaluate the safety, immunogenicity, and efficacy of INO-4800, a prophylactic vaccine against COVID19 disease, administered intradermally followed by electroporation in adults at high risk of SARS-CoV-2 exposure. **Unmet medical need in the country-** The test drug is used in prophylactic Vaccine

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			against COVID19 disease, administered intradermally followed by electroporation in adults at high risk of SARS-CoV-2 exposure. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III part of proposed Phase II/III clinical study.
SND Division			
4.	SND/CT/21/000084 Several therapies, including antiviral therapies	M/s Qascent Research Solutions	In light of recommendations of the earlier committee meeting held on 01.10.2021, the firm has presented the revised Phase III CT study protocol for approval. After detailed deliberation the committee recommended for grant of permission for conduct of the Phase III clinical trial as per the protocol presented subject to condition that the maximum daily dose of Paracetamol should be revised to 2g/day.
New Drug Division			
5.	ND/MA/20/000149 Purified aqueous extract of Cocculus	M/s Sun Pharmaceutical Industries Ltd.	The proposal was deferred to the next meeting, due to technical problem at applicant end, they said that they were unable to connect through link and requested to defer the proposal for the next meeting.