Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 143rd meeting held on 11.02.2021at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	X-11026/94/2020 BD Convalescent Plasma	M/s Wockhardt Hospitals, Mumbai	The firm presented Phase-II Clinical Study results on Convalescent plasma before the committee. The committee noted that there is no statistical significant difference in clinical outcome between treatment arm and control arm.
2.	X-11026/194/2020-BD COVID-19 Hyper Immune globulin (Human Solution)	M/s Intas Pharmaceuticals Pvt. Ltd	The firm presented Phase-II Clinical Study results on COVID-19 Hyper Immune globulin before the committee. After detailed deliberation, the committee opined that the Phase-II trial data presented did not show any statistical significant difference in efficacy with respect to primary and secondary endpoints between treatment arm and control arm. Therefore, the committee did not consider the request of the firm for approval for restricted emergency use of the product.
GCT Division			
3.	CT/09/2021 online submission (23712) BRII-196 and BRII-198	M/s PPD	Firm has presented Phase 3 version 2.0 clinical trial study protocol 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 study justify the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic option:** The Purpose of the study is To evaluate safety of the investigational agent. **Unmet Medical need in the country:** The test drug may potentially provide treatment in patients with COVID-19 (Adapt Out COVID). After detailed deliberation Committee recommended following- 1) Firm should centrally supply Identical

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			vials for both active and Placebo to maintain uniformity so that the blinding may be done properly. Also the randomization done centrally. 2) Firm should include sites from sites from different geographical regions of country and number of government institution should be increased. 3) List of prohibitory medicines should be mentioned in exclusion criteria. 4) Firm needs to submit PhaseII data for review before initiation of Phase-III. Accordingly firm should submit revised clinical trial protocol for further review by the committee.
4.	CT/08/2021 online submission (23690) Carrimycin	M/s Parexel	Firm presented the proposal for phase III clinical trial of the drug Carrimycin before the committee . Committee noted that drug is not approved for any indication anywhere in the world, except China and also phase I & II data is inadequate. Committee opined that, firm should follow the regulatory pathway for development of New drug as per rules and guidelines and submit robust Phase I & II data for further consideration by the committee.
5.	CT/14/2021 online submission (23828) SNG001	M/s Parexel	Firm presented their Phase III clinical trial proposal 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 study justify the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic option:** The Purpose of the study is the efficacy and safety of inhaled SNG001 for

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			the treatment of patients hospitalized due to moderate COVID-19. **Unmet Medical need in the country:** The test drug may potentially provide treatment of patients hospitalized due to moderate COVID-19. After detailed deliberation the committee recommended that firm should submit the following data for further review by the committee. 1) Details of the phase I and II clinical trials in Bronchial asthma, COPD and COVID-19. 2) Firm need to submit specific data related to Anti-SARSCOVID-19 activity of the Drug.
6.	CT/100/20 online submission (22101) Opaganib	M/s JSS	In light of earlier recommendation dated 20.11.2020, firm has presented their proposal before the committee. After detailed deliberation committee noted that the data presented shows high mortality (approx-18%) in 200 subjects. In another limited phase IIa study data presented by the firm (37 subjects) there was no mortality benefit or rate of deterioration. In view of high mortality the data should be unblinded to know the details of mortality in two groups. Accordingly, the firm should submit above information for review by the committee.
7.	CT/113/20 online submission (10762) Baricitinib	M/s Elililly	Firm presented their clinical trial proposal for increasing the sample size with additional 50 subjects before the committee. After detailed deliberation the committee noted that these 50 subjects to be included are in ordinal scale 7 which is not the part of original protocol or any subsequent amendments, Hence, the committee opined that permission for additional 50 subjects enrolment in ordinal scale 7 should not be granted.

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SND Division			
8.	SND/CT/21/000002 Niclosamide for the treatement of hospitalized COVID-19 patients	M/s Laxai Life Science	Firm did not turn up for presentation
9.	SND/CT/20/000021 Niclosamide IM depot injection 960 mg/4ml	M/s Daewoong pharmaceutical	Firm submitted Clinical study report of Phase I, Part A in healthy subjects for Niclosamide IM depot injection 960 mg/4ml before the committee. After the discussion the firm informed the committee about their plan to change the dose of the drug in the Phase I Part B Clinical trial. Accordingly, the committee recommended that the firm should submit the revised CT protocol for review by the committee.