Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 213th meeting held on 23.02.2022 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
New Drug Division			
1.	ND/MA/20/000066 Remdesivir Injection 100 mg/20 ml	M/s Hetero	The firm didn't turn up for presentation.
2.	12-01/20-DC Anti-corona virus therapies (Pt-333)	M/s St. John's, Bangalore	The firm didn't turn up for presentation.
3.	ND/MA/22/000028 Cannabidiol oral solution 150 mg/gm	M/s Zenera Pharma Pvt. Ltd.	The firm presented their proposal for manufacture and marketing of the drug alongwith Phase III CT protocol before the committee. After detailed deliberation, the committee recommended that firm should submit detailed pre-clinical/ animal data, single dose and repeated dose animal toxicity data, Phase I, II, III clinical data, regulatory approval status from other countries alongwith detailed justification for the proposed indication to CDSCO for further review by the committee.
4.	ND/CT/21/FF/2022/30448 Combi pack of Nirmatrelvir tablets 150 mg +Ritonavir Tablets 100mg in India	M/s Cipla Limited.	The firm presented their proposal for manufacturing and marketing of Combi pack of Nirmatrelvir tablets 150 mg +Ritonavir Tablets 100mg along with BE study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study as per the submitted protocol with the condition that the sample size in the study should be 48 subjects and washout period should be 7 days.
5.	ND/CT21/20/23164 Aviptadil Injection 150µg/ml(FF)	M/s Zuventus Healthcare	In light of the earlier recommendation of the SEC (COVID) meeting held on 21.01.2022, the firm presented their proposal and requested for emergency

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			approval of Aviptadil Injection 150 µg/ml before the committee. After detailed deliberation, the committee recommended that the firm should submit the complete Serial Lungs Images and RT-PCR test data of the trial patients at the earliest for further review by the committee.
Biological Division			
6.	X- 11026/219/2020-BD Covid-19 Hyper-Immune globulin (Human) solution	M/s Virchow Biotech Pvt. Ltd, Hyderabad (5%, 10 ML)	The firm presented Phase-II clinical trial report on COVID-19 Hyper-Immune globulin (Human) solution before the committee. The committee noted that the study was conducted in 66 moderate to severe COVID-19 patients. Out of this 66, only 6 patients were in severe category. The committee also noted that the study failed in primary efficacy end point. After detailed deliberation, the committee didn't recommend for approval of the proposed for conducting the Phase-III clinical trial.
7.	X- 11026/273/2021-BD CB-10 monoclonal antibody	M/s Dr. Reddy's Laboratories Limited	The firm didn't turn up for presentation.
GCT Division			
8.	CT/92/21 Proxalutamide (GT0918)	M/s. IQVIA	The firm didn't turn up for presentation.
9.	CT/51/21 C21	M/s. QED Clinical Services	The firm presented their proposal for protocol amendment for protocol no VP-C21-008 version 4.0 dated 07-Dec-2021. After detailed deliberation the committee recommended for grant of approval for the proposed protocol

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			amendment and to initiate the Phase III part of the study with 120 subjects in the country.
SND Division			
10.	SND/MA/22/000035 Remdesivir for Injection 100 mg/vial	M/s Mylan Laboratories Ltd.	The firm presented their proposal for manufacturing and marketing of Remdesivir for Injection 100 mg/vial for additional indication "for the treatment of Coronavirus disease 2019 (COVID-19) in Adults who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19" and requested for local clinical trial waiver. After detailed deliberation, the committee recommended that the firm should conduct a clinical trial in India. Accordingly, the firm should submit protocol for review by the committee.