Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 122nd meeting held on 04.11.2020 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	X.11026/134/2020-BD Intravenous Immunoglobulin (IVIG) Phase-II Clinical Study Report	M/s Virchow Biotech Private Limited, Hyderabad	Firm presented their Phase-II Clinical Trial data before the committee. During the presentation the firm informed that they did not find any significant difference between the control arm and study arm and they do not want to conduct further clinical trial with this drug. Committee noted the same.
2.	X.11026/219/2020-BD COVID-19 Hyper-Immune Immunoglobulin	M/s Virchow Biotech Pvt. Ltd, Hyderabad	Firm presented their Phase-II Clinical Trial protocol before the committee. Committee opined that firm should justify the selection of dose, inclusion and exclusion criteria as well as outcome measures. After detailed deliberation, committee recommended that the firm should revise the protocol as above and present before the committee for further review.
3.	BIO/CT21/BO/2020/22029 Pegylated Interferon Alfa 2b injection in the treatment of moderate COVID 19 infection	M/s Cadila Healthcare Limited	The firm presented the results of the Phase II Clinical Trial and their proposal for grant of Emergency Use Authorization for the treatment in moderate COVID 19 patients, The committee noted that the data was generated only in 40 patients. After detailed deliberation, the committee recommended that available data is not adequate for grant of permission for emergency use of the drug in COVID 19 patients.
GCT Division			
4.	CT/112/20(22464) JS016	M/s.Parexel	Firm presented the Phase-Ib/II Clinical Trial protocol before the committee. **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 preliminary efficacy of intravenous infusion of JS016 in participants with mild and moderate COVID-19 or of SARS-CoV-2

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			asymptomatic infection; **Unmet medical need in the country-** The test drug used for treatment with JS016 given as Intravenous Infusion in Participants with Mild and Moderate COVID-19 or of SARS-CoV-2 Asymptomatic Infection. After detailed deliberation, committee recommended for grant of permission to conduct the Clinical Trial Ib/II subject to the following conditions: 1. Asymptomatic patient should not be included in the study. 2. The patients with SpO2 level between 90 to 93 fulfilling the criteria of moderate patients should be included in the study. 3. Plastic surgeon should not be PI in the study. It was presented that one plastic surgeon is PI in the study.
5.	CT/113/20(22384) Baricitinib	M/s.Eli Lilly	Firm presented the Phase-III Clinical Trial protocol before the committee. **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 effect of baricitinib 4-mg once daily (QD) compared to placebo on disease progression in patients with COVID-19 infection. **Unmet medical need in the country-** The test drug used for treatment with Baricitinib in Patients with COVID-19 Infection. After detailed deliberation the committee recommended for grant of permission to conduct the Phase-III Clinical Trial subject to the conditions that details of corticosteroids use should be clarified.

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6.	CT/115/20(22459) RBT-9	M/s.JSS	Firm presented the Phase-II Clinical Trial protocol before the committee. After detailed deliberation the committee recommended that firm should submit the following data: 1. PK study data in terms of Absorption, Distribution, Metabolism & Excretion of the drug. 2. Animal data in support of claim of anti-viral efficacy of the drug against COVID-19. 3. Animal PD data in support of claim for organ protective effect of the drug. 4. Status of Clinical Trials in USA and other countries. Accordingly firm should submit the above documents to CDSCO for review by the committee.
SND Division			
7.	12-01/2020-DC (Pt-NSRT-SND) Eflornithine (Eflornithine Granules 2.5gm & 5.0gm)	M/s Navin Saxena Research & Technology	In light of earlier recommendation of the SEC meeting dated 29/10/2020, the firm presented the Phase IIb Clinical Trial protocol before the committee. After detailed deliberation the committee recommended to revise the design of Clinical Trial to conduct a superiority trial of the product against SoC in moderate Covid-19 cases with following conditions: 1. SoC should be defined as per Government of India guideline and shall be uniform across all the trial sites. 2. SoC should be administered in all the treatment arms. 3. Patients with age of 18 to 65 years to be included in the study. 4. Severity criteria should be defined as per Govt. of India guidelines.

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			5. Eflorithine 10g/day in divided dose should be used in the test arm. 6. Management of treatment failure patients to be defined in the protocol 7. Change in two-point improvement in clinical efficacy as per WHO ordinal scale should be Primary end point. 8. Assessment of Mortality rate in 28 days should be one of the secondary end points. 9. Proper justification for sample size should be provided.