Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 187th meeting held on 04.10.2021 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
New Drug Division			
1.	ND/MA/21/000046 Molnupiravir 200 & 400 mg capsules	M/s Strides	The firm presented their proposal for proposed amendments before the committee. The committee after detailed deliberations recommended for approval of proposed amendments in respect of RT-PCR negativity assessment at Day3 instead of Day 14 and assessment of C Reactive Protein (CRP). The primary endpoint will remain the same.
2.	ND/MA/21/000052 Molnupiravir 200 & 400 mg capsules	M/s MSN	The firm presented the interim Clinical Trial data in moderate COVID-19 patients. During meeting the firm stated that, they want to discontinue Phase III trial in moderate COVID-19 Patients and continue the Phase III trial in mild COVID patients. The committee opined that the firm should submit above in writing to CDSCO for further consideration.
3.	ND/MA/21/000074 Molnupiravir Capsules 200mg	M/s. Aurobindo Pharma Limited	The firm presented the interim Clinical Trial data in moderate COVID-19 patients. During meeting firm stated that, they want to discontinue Phase III trial in moderate COVID-19 Patients continue the Phase III trial in mild COVID patients. The committee opined that the firm should submit above in writing to CDSCO for further consideration.
GCT Division			
4.	CT/107/21 CKD-314	M/s. Kendle	The firm presented their proposal for phase III clinical study 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 and Phase I &II clinical study data justify the conduct of the trial.

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			Innovation vis-à-vis Existing Therapeutic option: The Purpose of the study is To evaluate the efficacy and safety of CKD-314 by comparing the study group(CKD-314 + standard of care) and control group (placebo of CKD-314+standard of care) in hospitalized adult patients diagnosed with COVID-19 pneumonia. **Unmet Medical need in the country:** The test drug may potentially provide treatment in Hospitalized Adult Patients Diagnosed with COVID-19. The committee, after detailed deliberation recommended for grant of permission to conduct the phase III clinical study subject to the following conditions : 1. The firm should include patient with RTPCR positive test in the study. 2. In primary endpoint firm should clarify time to assess the efficacy parameters. 3. Proposed IMP is marketed with name Nafabelltan in Japan since last 20 years. Hence the firm needs to clarify why they are using IMP code instead of the proper name of the drug to conduct this study.
5.	CT/112/21 Deupirfenidone (LYT-100)	M/s. Syngene	The firm presented their proposal for phase II clinical study before the committee. **Assessment of risk vs. Benefit to the patients:** The safety profile of the study drugs from preclinical toxicology studies. **Innovation vis-à-vis Existing Therapeutic option:** The Purpose of the study is to assess the long-term safety, tolerability and efficacy of LYT-100. **Unmet Medical need in the country:** The test drug may potentially provide treatment for the COVID-19 Patients. The committee after detailed deliberation recommended for grant of permission to conduct of the proposed Phase-II clinical trial as per the protocol.

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6.	CT/113/21 PF 07321332 /Ritonavir	M/s. Pfizer	Firm did not turn up for presentation.
7.	CT/115/21 ADG20	M/s. PPD	The firm presented the proposed Phase 2/3 clinical study protocol no. ADG20-TRMT-001, Version 4.0 dated 06MAY2021 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-** Evaluate the Efficacy and Safety of ADG20 in the Treatment of Ambulatory Participants with Mild or Moderate COVID-19 (STAMP) **Unmet medical need in the country-** The test drug used for treatment of ambulatory participants with mild or moderate COVID-19 (STAMP). After detailed deliberation, the Committee recommended for grant of permission to conduct the study with the following conditions: 1) The firm should submit the safety data from the phase II part of the study along with IDMC recommendation before the Committee for review and only thereafter the Phase III part of the study may only be initiated. 2) The study Investigator should be atleast MD (Medicine/ Pulmonologist).
8.	CT/54/21 SARS-CoV-2 Adjuvanted Recombinant ProteinVaccines	M/s. Sanofi	The firm presented the NHP data in compliance with the CT NOC condition no. 2, and proposed protocol amendment to protocol no. VAT00008, Version 4.0 dated 11AUG2021 before the Committee. After detailed deliberation, the Committee recommended to continue the second phase of the trial as per CT NOC and recommended the proposed protocol amendment as presented along with increase to1000 subjects from India.

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9.	CT/37/21 SIR1-365	M/s. JSS	Firm did not turn up for presentation.
10.	CT/69/21 PF 07321332 /Ritonavir (Additional Agenda)	M/s Pfizer	In light of earlier SEC dated 01-10-2021 comments, the firm presented the rational and comparison of protocol amendment 2.0 dated 02AUG2021 and Protocol amendment 1.0 dated 02JUL2021 w.r.t initial protocol no. C4671005 dated 18JUN2021 before the committee; during presentation the firm stated that there is no proposal for increase of sample size from India in its presented Protocol amendment 2.0. After detailed deliberation, the Committee recommended for the approval of the protocol amendment 2.0 along with protocol amendment 1.0 as presented.