Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 112th meeting held on 28.09.2020 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	File No. -12-01/20-DC (Pt.-333) Anti corona virus therapy	St. John's National Academy of Health Sciences	In light of earlier recommendation dated 01-09-2020 the applicant presented their justification etc for the clinical trial protocol. The committee noted that all the four drugs (interferon, colchicine, aspirin & rivaroxaban) are now experimental drugs for COVID-19 patients. The committee is of the opinion that use of four experimental drugs in different combinations, in this life threatening condition, as proposed in the Clinical Trial, is not justified. Therefore, after detailed deliberation committee did not recommend for approval of the proposed Clinical Trial.
2.	F.NO. ND/MA/20/00084 Remedesivir 100mg/vial	M/s Mylan	The applicant presented the active PMS protocol before the committee. After detailed deliberation the committee recommended for grant of permission to conduct active PMS as per the protocol presented.
3.	F, No. ND/MA/20/000137 Umifenovir Hydrochloride capsule 50/100/200mg	M/s Macleods	The application of the firm is for approval of Umifenovir HCl in COVID-19. However, the firm presented their proposal for clinical trial of Umifenovir and Favipiravir along with standard supportive care verses favipiravir along with standard supportive care in hospitalized subjects with moderate COVID-19 Infection. After detailed deliberation the committee recommended that firm should submit appropriate protocol for evaluation of safety & efficacy of Umifenovir Hydrochloride Capsules as their application is for approval of Umifenovir Hydrochloride single drug.

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		GCT Division	
4.	CT/90/20 Online Submission (21876) Bemcentinib (BGB324)	M/s. IQVIA	Firm presented their proposal along with the Phase II clinical trial protocol before the committee. **Assessment of Risk vs. Benefit to the patients**: The safety profile of the study drug (as anticancer) from preclinical toxicology studies including repeat dose toxicity,Phase-I& IIclinical study(oncology category) is defined. One*in vitro* (*Vero* E6 cell lines) antiviral study and additional studies viz. vesicular stomatitis virus peusdotyped with SARS-CoV spike protein and mouse beta coronavirus (MHV) justify the conduct of the Phase II trial. **Innovation vis-à-vis Existing Therapeutic option:** The purpose of the study is to assess the safety and efficacy of Bemcentinib (BGB324) a new chemical entity for the treatment of COVID-19 in hospitalised patients with primary (efficacy) objective and other secondary objectives. **Unmet Medical need in the country:** As on date there was no approved and effective treatment for COVID-19. After detailed deliberation the committee recommended for grant of permission to conduct the clinical trial subject to following condition- 1) Inclusion criteria should be revised - "To include the COVID-19 patients (Grade 4 & 5 as per 9-point WHO ordinal scale) also fulfilling the Indian guidelines criteria of moderate COVID-19". 2) Sample size in India should be 60 (30 in each arm). 3) There should be DSMB as per the guidelines for safety monitoring of the trial.
5.	CT/91/20 Online Submission (21905) IFX-1	M/s. Parexel	The firm has presented the Phase 2/3 protocol before the committee. **Assessment of risk versus Benefit to the patient:** The safety profile of the study drug from various pre-clinical toxicology studies and clinical studies- Phase I and Phase II studies, justify the

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			conduct of the study. **Innovation vis –a- vis exiting therapeutic:** To demonstrate the efficacy of IFX-1 to improve survival outcomes of severe COVID- 19 pneumonia. **Unmet Medical need in the country:** The test drug may potentially provide treatment in patients with Severe COVID-19 Pneumonia. The committee noted that in Phase II trial, it did not met the primary endpoint. Therefore, after detailed deliberation, committee did not recommend for approval of the proposed Phase III Clinical Trial.