Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 192nd meeting held on 17.11.2021 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
GCT Division			
1.	CT/118/21 Baricitinib	M/s. Eli Lilly	The firm presented their proposal for phase III clinical trial before the committee. After detailed deliberation, the committee noted that the primary endpoint was not met in the phase III adult trial with the proposed IP. Hence the Committee did not recommend for grant of permission to conduct the proposed pharmacokinetic study in the paediatric subjects.
2.	CT/106/21 SNG001 &/or SAB-185	M/s. PPD	The firm presented the proposed adaptive platform study protocol no. ACTIV-2/A5401, Version 7.0 dated 29JUN2021 & LOA#1 dated 30JUL2021 before the Committee. The Committee noted that only the proposed phase III part of the study will be conducted in India with the Investigational products i.e. SNG001 and SAB-185 (dose 3840 U/kg) in the proposed study After detailed deliberation the committee recommended for grant of permission to conduct the presented study with the following conditions: 1) The firm should submit the phase II interim analysis data, when available. 2) The study Investigator should be MD (Medicine or Pulmonologist). 3) Atleast 50% Govt. sites geographically distributed in the country should be selected. The committee also desired that the firm should submit the trial status of already approved protocol no. ACTIV-2/A5401, Ver 2.0 dt. 23Nov2020 (with IP-BRII-196 & BRII-198) before the Committee.
3.	CT/132/21 Brequinar	M/s. Veeda	The firm presented the proposed phase II (CCB-CRISIS-04) study protocol no. 21-VIN-0372, Ver. 2.0 dated 30Sep2021 before the Committee.

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			After detailed deliberation, the committee recommended for grant of permission to conduct the study with the condition that the firm should conduct first the Part 1 of the proposed study and submit its data along with DSMB report for review by the Committee for further continuation of the part II (expansion part) of the study.
4.	CT/139/21 Allogeneic Mesenchymal Stem Cells	M/s. Biorasi CRO Services	The firm presented the proposed phase II study protocol no. STEM-107-COVID-19, Revision 01, dated 22JAN2021, before the Committee. After detailed deliberation, the Committee recommended for grant of permission to conduct the study with the following conditions: 1) The study should be first conducted in five Indian subjects and its safety data along with DSMB report should be presented before the Committee for review and after the review, the study may be further continued. 2) The firm should define the standard of care for COVID-19 as per the guidelines of Govt. of India/ICMR and it should be uniformly implemented at all participating clinical trial sites in India.
5.	CT/99/21 Ad26.COV2.S	M/s. J&J	The firm presented their proposal for protocol amendment for protocol no. VAC31518COV3006, Amendment 2, dated 26.10.2021. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
6.	CT/133/20 EDP1815	M/s. Spectra Hospital Services	The applicant did not turn-up for presentation.