

Recommendations of the SEC meeting to examine (COVID-19) related proposal under accelerated approval process made in its 236th meeting held on 17.10.2022 at CDSCO (HQ), New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/IMP/21/000034 Monoclonal Antibody (Casirivimab 120mg/ml Imdevimab 120mg/ml injection)	M/s Roche Products(I) Pvt. Ltd.	The firm presented the report of post marketing surveillance study “A Non-interventional observational study assessing safety and efficacy of neutralizing monoclonal antibody (Casirivimab / Imdevimab) treatment in a real world-setting of mild/moderate Covid-19 patients in India” protocol no. ML43553 version 2.0 dated 26.05.2021 as per the condition mentioned in the permission granted to the firm to import & market the drug Casirivimab 120 mg/mL and Imdevimab 120 mg/mL for ‘Restricted use in emergency situation for treatment of mild to moderate COVID-19’ in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with laboratory confirmed SARS-COV2 infection and who are at high risk of severe COVID-19 and does not require oxygen. After detailed deliberation, the committee noted the results of the presented PMS study.
New Drug Division			
2.	ND/MA/20/000166 Aviptadil for Injection	M/s MSN	The firm didn’t turn up for presentation.
GCT Division			
3.	CT/76/22 S-217622	M/s IQVIA	The firm presented the Phase III clinical trial study Protocol number: ACTIV-2d/A5407 Version 3.0 dated 23 June 2022. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed study as presented.
4.	CT/94/22 FB2001	M/s IQVIA	The firm presented the Phase II/III study protocol no. FB2001-301 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed study as presented.
5.	CT/94/21 Anti-coronavirus Hyper immune Intravenous	M/s ICMR	The firm presented the Protocol Amendment Version No. 1.1 dated 14/June/2022 to Clinical Trial Protocol Number: INSIGHT

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	Immunoglobulin		012 version No. 1.0 dated 08/April/2021. After detailed deliberation, the committee recommended for grant of permission to presented the protocol amendment Version No. 1.1 dated 14/June/2022 as presented.