

Recommendations of the SEC (Cardiovascular & Renal) made in its 138th meeting held on 28.11.2023 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/118/23 Online Submission (39700) BI 456906 Survodutide	M/s. IQVIA RDS	The firm presented Phase III Clinical study Protocol no. BI 456906. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that 1. Atleast 50% trial sites should be govt. sites & atleast 50% subjects shall be enrolled from govt. sites. 2. Investigators in the study should be Cardiologist only. 3. Co-medication & Other treatment including follow up should be borne by the sponsor.
2.	CT/116/23 Online Submission (39668) Sibeprenlimab (VIS649)	M/s. George Clinical India	The firm presented Phase 2/3 Clinical study Protocol no. 417-201-00012. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/114/23 Online Submission (39566) Baxdrostat Tablets 1mg/ 2mg/Placebo	M/s. AstraZeneca	The firm presented Phase III Clinical study Protocol no. D6970C00002. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that 1. Atleast 50% trial sites should be govt. sites & Atleast 50% subjects shall be enrolled from govt. sites. 2. Investigators in the study should be Cardiologists only. 3. Co-medication & Other treatment including follow up should be borne by the sponsor.
4.	CT/136/22 Online Submission (28040) Sodium Zirconium Cyclosilicate	M/s. AstraZeneca	The firm presented Protocol amendment version 3.0 dated 04 Apr 2023 Protocol no. D9487C00001. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.

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5.	CT/111/21 Online Submission (28279) Inclisiran	M/s. Novartis	The firm presented Protocol amendment version 02 dated 10 July 2023 Protocol no. CKJX839B12302. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
6.	CT/63/21 Online Submission (28535) Ziltivekimab	M/s. Novo-Nordisk	The firm presented Protocol amendment version 11.0 dated 17 May 2023 Protocol no. EX6018-4758 (ZEUS). After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.