

Recommendations of the SEC (Renal) made in its 07th/25 meeting held on 22.07.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/80/25 Online Submission (50141) Atacicept	M/s Worldwide Clinical Trials India Private Limited	The firm presented phase II clinical study Protocol No.: VT-001-0020 Version No. 1.0 dated 07-FEB-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1. Rescue therapy plan shall be mentioned for the high dose of intervention drug in the protocol. 2. Liver function test and Renal function test (inclusive of urea and creatinine) shall be performed. 3. The specific rescue plan for deteriorating condition of participating subject shall be included in the study.
2.	CT/78/25 Online Submission (50002) VAY736 (Ianalumab)	M/s Novartis Healthcare Private Limited	The firm presented phase III clinical study Protocol No.: CVAY736K12301E1 Version No. 00 dated 14-AUG- 2024. After detailed deliberation, the committee opined that the proposed design of study protocol is not approved in the present format due to following reasons: i.) The rationale for continuing treatment with the trial drug in an individual who did not respond to treatment with the same for 144 weeks is unclear.

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			<p>ii.) A patient who was either in the two intervention arms or the placebo arm, who did not attain Partial Renal Response and Complete Renal Response may be offered enrollment in the Open Label Extension study, and the patient needs to continue the existing treatment regimen (Standard of Care). Despite incomplete response. The rationale for this need to be clarified.</p> <p>Accordingly, firm is required to submit the clarification and detailed data for further review by the committee.</p>
3.	<p>CT/152/24 Online Submission (40041)</p> <p>Baxdrostat Tablets 1 mg/ Placebo</p> <p>Baxdrostat Tablets 2 mg/ Placebo</p> <p>Dapagliflozin Tablets 10 mg</p>	<p>M/s AstraZeneca Pharma India Limited</p>	<p>The firm presented protocol amendment version 3.0 dated 30 April 2025 protocol no. D6972C00002.</p> <p>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.</p>
4.	<p>CT/133/24 Online Submission (40063)</p> <p>Atacicept</p>	<p>M/s Medpace Clinical Research India Pvt. Ltd.</p>	<p>The firm presented protocol amendment 1.0 dated 24 April 2025 protocol no. VT-001-0051.</p> <p>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.</p>