

**Recommendations of the SEC (Renal) made in its 01<sup>st</sup> meeting held on 20.02.2024 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/77/22 Online Submission (30148)  Crovalimab 170 mg/ml Crovalimab 340 mg/2m	M/s. Roche Products	The firm presented protocol amendment version 4 dated 29 July 2022 and protocol amendment version 5 dated 18 May 2023, protocol No.:BO42354.  After detailed deliberation, the committee recommended for approval of protocol amendments as presented by firm.
2.	CT/135/23 Online Submission (40226)  Tebipenempivoxil hydrobromide (TBP-PI-HBr, previously known as SPR994)	M/s. PSI CRO Pharma Pvt. Ltd.	In light of earlier SEC recommendation dated 06.12.2023 and 07.12.2023, the firm presented Phase III clinical study protocol No.SPR994-305.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by firm with condition on submission of USFDA special agreement for protocol review shall be submitted to CDSCO.
3.	CT/43/21 Online Submission (29948)  Atacicept	M/s. Medpace Clinical Research India Pvt. Ltd.	The firm presented Phase IIb protocol amendment 6 dated 23 August 2023 protocol No. VT-001-0050.  After detailed deliberation, the committee opined that protocol shall be revised with respect to following for further review of the committee:  a. Changes of RAASi medication and SGLT 2 inhibitors. b. Protocol for management of overdose and toxicity to be specified. c. No extra volume of biological sample should be collected for biomarker assessment.”
4.	CT/65/23 Online Submission (29991)  Atacicept	M/s. Medpace Clinical Research India Pvt. Ltd	The firm presented Phase 2b/3 protocol amendment 6 dated 23 August 2023 protocol No. VT-001-0050.  After detailed deliberation, the committee opined that protocol shall be revised with respect to following for further review of the committee:  a. No extra volume of biological sample collected for biomarker

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			<p>assessment.</p> <p>b. Changes of RAASi medication and SGLT 2 inhibitors.</p> <p>c. Definitions shall be revised as per the standard guidelines.</p>
5.	<p>CT/165/23 Online Submission (41088)</p> <p>LNP023 (Iptacopan)</p>	M/s. Novartis	<p>The firm presented Phase IIIb clinical trial study protocol No. CLNP023F12001B.</p> <p>After detailed deliberation, the committee opined that following information to be submitted for further review by the committee.</p> <p>a. Serial number 3 of inclusion criteria should be revised for more objectivity, defining objective criteria based on which the investigator will assess that the participant has benefitted.</p> <p>b. In the section describing duration for which the study drug will be provided to participants, conditions number 2 and 3 should be defined more objectively. “(Participants no longer derives benefit from Iptacopan” and the benefit-risk profile of the product is no longer positive)”.</p> <p>c. In exclusion criteria, women of child bearing potential should be redefined.</p> <p>d. Explanation for spontaneous abortion to be provided.</p>
6.	<p>CT/23/000017 Online Submission (30942)</p> <p>Finerenone</p>	M/s. Fortrea	<p>The firm presented protocol amendment version 2.0 dated 24 Oct 2023, protocol No.:21839.</p> <p>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by firm.</p>
7.	<p>CT/48/22 Online Submission (30800)</p> <p>LNP023 (Iptacopan)</p>	M/s. Novartis Healthcare Private Limited	<p>The firm presented protocol amendment version 01 dated 29 Jul 2023, protocol No.CLNP023K12201.</p> <p>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by firm</p>
8.	<p>CT/24/000009 Online Submission</p>	M/s. AstraZeneca	<p>The firm presented Phase IIIb clinical trial study protocol No. D4325C00010, version 1.0 dated 27 Aug 2023.</p>

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	(41468)  Zibotentan 0.25mg + Dapagliflozin 10mg & Zibotentan .75mg + Dapagliflozin 10mg		After detailed deliberation, the committee opined that the firm shall submit revised protocol incorporating definition of CKD as per standard guidelines, defining persistent high proteinuria, type of patients to be enrolled in inclusion criteria etc. for further review by the committee.
9.	CT/52/23 Online Submission (37573)  LNP023/Iptacopan	M/s. Novartis	In light of earlier SEC recommendation dated 09.08.2023, the firm presented Phase IIIb clinical study protocol No. CLNP023B12001B, version 03 dated 25 July 2022.  After detailed deliberation, the committee opined that the firm did not address the issue in light of previous SEC recommendation based on which permission was denied earlier.  Therefore, the proposed open label study cannot be considered.
<b>SND Division</b>			
10.	SND/MA/23/000208  Tacrolimus Extended Release Tablets 0.75mg, 1mg & 4mg	M/s. Intas Pharmaceuticals Limited	The firm presented their proposal for grant of permission to manufacture and marketing of Tacrolimus extended release tablets 0.75mg, 1mg & 4mg with justification for waiver of clinical trial. The firm presented the Bioequivalence study reports for Tacrolimus extended release tablets 1mg and 4mg in fasting & fed condition before the committee and informed that Tacrolimus extended release tablets 0.75mg, 1mg & 4mg are approved by USFDA and EMEA.  After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Tacrolimus extended release tablets 0.75mg, 1mg & 4mg with the condition that the firm should conduct the Phase-IV clinical trial study. In addition to above the firm should fulfill the requirement of CMC data.  Accordingly, the firm should submit Phase-IV clinical trial protocol to CDSCO within 03 months from date of approval of drug for further review by the

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			committee
<b>FDC Division</b>			
11.	FDC/MA/23/000327  Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin + Telmisartan IP (10mg+40mg/ 10mg+80mg) tablet	M/s. Exemed Pharmaceuticals	In light of the earlier SEC recommendation dated 22.11.2023, the firm presented BE study report before the committee.  After detailed deliberation, the committee considered the BE study report and recommended to initiate Phase III clinical trial for which permission has already been granted by CDSCO. The result of Phase III clinical trial should be presented before the committee for review.