

Recommendations of the SEC (Renal) made in its 09th/25 meeting held on 18.09.2025 at CDSCO HQ New Delhi:

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---------------------|--|---|--|
| GCT Division | | | |
| 1. | CT/121/25 Online Submission (51423) Mezagitamab (TAK-079) | M/s. PPD Pharmaceutical Development India Private Limited | The firm presented phase III clinical study protocol no.: TAK-079-3001 version no. original dated 14-MAR-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that if medically indicated, the patient should have post - trial access to the drug, even if the patient has been withdrawn from the trial prematurely. |