

Recommendations of the SEC (Renal) made in its 06th/24 meeting held on 10.07.2024 at CDSCO (HQ), New Delhi:

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---------------------|--|---|--|
| GCT Division | | | |
| 1. | CT/115/20 Online Submission (32704) LNP023 | M/s. Novartis Healthcare Private Limited | The firm presented protocol amendment version 04 dated 15 February 2024 protocol no. CLNP023A2301. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. |
| 2. | CT/09/24 Online Submission (41468) Zibotentan 0.25mg or 0.75mg + Dapagliflozin 10mg | M/s. AstraZeneca Pharma India Limited | In light of earlier SEC recommendation dated 20.02.24, the firm presented phase 3 clinical study protocol no. D4325C00010 version 1.0 dated 27 August 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. |
| 3. | CT/22/24 Online Submission (33451) Baxdrostat Tablets 1mg/Placebo Baxdrostat Tablets 2mg/ Placebo Dapagliflozin Tablets 10 mg | M/s. AstraZeneca Pharma India Limited | The firm presented protocol amendment version 3.0 dated 15 March 2024 protocol no. D6972C00003. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. |
| 4. | CT/63/21 Online Submission (33560) Ziltivekimab 15 mg/ml | M/s. Novo Nordisk India Pvt. Ltd. | The firm presented protocol amendment version 12.0 dated 04 April 2024 protocol no. EX6018-4758. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. |
| 5. | CT/126/23 Online Submission (33613) BION-1301 (zigakibart) | M/s. PPD Pharmaceutical Development (India) Pvt. Ltd. | The firm presented protocol amendment 4 version 5.0 dated 6 May 2024 protocol no. CHK02-02. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. |
| 6. | CT/79/24 Online Submission (43782) BAY 3283142 | M/s. Bayer Pharmaceuticals Pvt. Ltd. | The firm presented phase 2b clinical study protocol no. 22040 version 2.0 dated 16 November 2023. |

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---------------------|--|--|---|
| | | | After detailed deliberation, the committee recommended for grant of permission to conduct the trial with condition that 1. Any major cardiac and kidney adverse events reported during the trial, the study drug needs to be stopped immediately and subjects need to be withdrawn from the study. |
| 7. | CT/86/24 Online Submission (44106) Sodium zirconium cyclosilicate (SZC) | M/s. Fortrea Development India Private Limited | The committee opined that the proposal will be deliberated in presence of pediatric nephrologist. |
| SND Division | | | |
| 8. | SND/IMP/24/000022 Empagliflozin Tablets 10mg and 25 mg | M/s. Boehringer Ingleheim | <p>The firm presented their proposal for import and marketing of Empagliflozin tablets 10mg and 25 mg for the indication to reduce the risk of sustained decline in eGFR, end-stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease at risk of progression (Additional indication) along with Global clinical trial data before the committee.</p> <p>The firm has informed that they are already holding permission to import and marketing of Empagliflozin tablet 10mg and 25mg for the indication to reduce the risk of sustained decline in eGFR (only for 30-90ml/min/1.73m²), end-stage kidney disease, renal death, cardiovascular death, and all cause hospitalization in adults with chronic kidney disease.</p> <p>After detailed deliberation the committee opined that the firm should submit stratified age group clinical trial data on Indian population or submit Phase-III clinical trial protocol to CDSCO for further review by the committee.</p> |