

Recommendations of the SEC (Oncology) made in its 38th/25 meeting held on 23.12.2025 at CDSCO HQ New Delhi:

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| GCT Division | | | |
| 1) | CT/83/25 Online Submission (50214) QL2107 Injection | M/s. Syneos Health India Private Limited. | <p>In light of earlier SEC recommendation dated 29.07.2025, the firm presented phase III clinical study protocol no. QL2107-102, version 1.0 dated 03 March 2025.</p> <p>After detailed deliberation, the committee opined that the proposed clinical trial is focused completely on Pharmacokinetic (PK) parameters. Moreover, primary objective and secondary objective of phase-III study protocol has not been demonstrated for confirmation of therapeutic benefit and efficacy end point. Hence, the committee didn't recommend to conduct the clinical trial in India.</p> <p>Now the firm presented justification (pK) parameters. Moreover, primary objective and secondary objective of phase-III study protocol of therapeutic benefit and efficacy end point.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.</p> <p>The data generated shall not be considered for marketing authorization in India.</p> |
| Biological Division | | | |
| 2) | BIO/CT04/FF/2025/49 869 Nivolumab Injection 100 mg/10mL vial. | M/s. Enzene Biosciences Ltd. | <p>In light of earlier recommendation of SEC (Oncology) dated 11.09.2025, the firm presented revised protocol to conduct a Phase III clinical trial titled "A phase III, prospective, multicenter, randomized, double blind, parallel group study to compare the efficacy and safety of proposed biosimilar Nivolumab versus innovator Nivolumab in patients with recurrent locoregional or metastatic squamous cell carcinoma of the head and neck (SCCHN) in adults progressing on or after platinum-based therapy" as per Protocol No. ALK43/ENZ132-NIVO1 Version 2.0, Dated 06/Oct/2025.</p> |

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| | | | <p>After detailed deliberation, the committee recommended following changes in the presented protocol: -</p> <ol style="list-style-type: none"> 1. ORR should be the primary endpoint. 2. All PIs should be Medical Oncologist. 3. Day care facilities should not be used as a clinical trial site 4. Clinical trial sites should be geographically distributed 5. Post-trial access of the study drug shall be provided to the subjects until disease progression. <p>Accordingly, the revised protocol shall be submitted to CDSCO for further evaluation by the committee.</p> |
| 3) | <p>BIO/CT18/FF/2025/51992</p> <p>Durvalumab Solution for Infusion 120 mg/2.4 mL and 500 mg/10 mL.</p> | <p>M/s. AstraZeneca Pharma India Limited.</p> | <p>The firm presented the proposal for the approval of following additional indication of the drug Durvalumab Solution for Infusion 120 mg/2.4 mL and 500 mg/10 mL based on the results of global clinical trial along with a request of waiver of Phase III clinical trial in India.</p> <p>Durvalumab in combination with carboplatin and paclitaxel is indicated for the first-line treatment of adults with primary advanced or recurrent endometrial cancer who are candidates for systemic therapy, followed by maintenance treatment with: --</p> <ul style="list-style-type: none"> •Durvalumab as monotherapy in endometrial cancer that is mismatch repair deficient (dMMR) <p>The committee noted that the drug is already approved for the proposed indication in EU, USA, Japan, Australia, and Canada and there is sufficient safety data available in Indian population.</p> <p>After detailed deliberation, the committee recommended for the approval of proposed additional indication in line with EMA approved indication with the condition that firm should conduct Phase IV study in India for the approved indication.</p> |

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| | | | Accordingly, the firm should submit Phase IV study protocol to CDSCO within three months of approval of additional indication. |
| 4) | BIO/CT04/FF/2025/51 502 Pembrolizumab Solution for Infusion 100 mg /4 mL Vial (25 mg/mL). | M/s. Enzene Biosciences Ltd. | <p>The firm presented the proposal to conduct a clinical trial titled- “A Phase III, multicenter, randomized, double blind, parallel group, comparative study to evaluate the efficacy, safety, pharmacokinetics and immunogenicity of proposed biosimilar Pembrolizumab versus KEYTRUDA® (Pembrolizumab) in combination with pemetrexed and platinum based chemotherapy in adult patients with Metastatic Non-Small Cell Lung Cancer” vide Protocol No.: ALK46/ENZ146-PEM1, Version No.: 1.0, Dated 07-July-2025.</p> <p>After detailed deliberation, the committee recommended following changes in the presented protocol</p> <ol style="list-style-type: none"> 1. ORR should be the primary endpoint. 2. The non-inferiority margin used for sample size calculation should be narrowed. 3. The PK study should be adequately powered. 4. Safety assessment should be done for at least 1 year. 5. All PIs should be Medical Oncologist. 6. Day care facilities should not be used as a clinical trial site. 7. Clinical trial sites should be geographically distributed. 8. Post-trial access should be provided until disease progression. <p>Accordingly, firm should submit the revised protocol to CDSCO for further evaluation by the committee.</p> |
| 5) | BIO/CT04/FF/2025/52 329 Nivolumab 10mg/ml concentrate for solution for infusion. | M/s. Shilpa Biologicals Private Limited. | The firm presented the proposal to conduct a clinical trial titled- “A Phase I/III, Randomized, Multicentre, Double Blind, Two-Arm, Parallel-Group, Comparative Clinical Study to Investigate the Efficacy, Immunogenicity, Safety, and |

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| | | | <p>Pharmacokinetics of SBPL-Nivolumab Biosimilar Versus Reference Nivolumab in study participants with Locally Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC)” vide Protocol No.: 25-AGCR-004, Version No.: 2.0, Dated 08-Dec-2025.</p> <p>After detailed deliberation, the committee recommended the following changes in the presented protocol-</p> <ol style="list-style-type: none"> 1. PFS and DOR should be the study endpoints. 2. All PIs should be Medical Oncologist. 3. Day care facilities should not be used as a clinical trial site. 4. Clinical trial sites should be geographically distributed. 5. Post-trial access should be provided until disease progression. 6. Complete results of the study shall be submitted instead of proposed submission of interim PK study results. <p>Accordingly, firm should submit the revised protocol to CDSCO for further evaluation by the committee.</p> |
| SND Division | | | |
| 6) | SND/IMP/25/000096 Lutetium Lu 177 vipivotide tetraxetan solution for injection or infusion 1000 MBq/mL | M/s. Novartis Healthcare Private Limited. | <p>The firm presented the proposal for grant of permission for the additional Indication of the already approved product along with request for local Phase III clinical trial wavier and proposal to conduct the Phase IV clinical trial before the committee.</p> <p>The committee noted that the product is approved in US & Japan (2025) in the applied indication. Further, the proposed product is already approved in India on 27.07.2025 for the indication “Treatment of adult patients with prostate-specific membrane antigen PSMA-Positive meta state castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based Chemotherapy” along with the condition to conduct Phase IV clinical trial.</p> <p>The SEC and AERB experts opined that</p> |

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| | | | <p>that there is unmet medical need for the proposed indication.</p> <p>After detailed deliberation, the committee recommended for grant of permission in applied indication with the condition to conduct Phase IV clinical trial.</p> <p>Further, the committee also opined that the firm should submit and present the Phase IV protocol of earlier permission before the grant of approval in applied indication.</p> |
| 7) | <p>SND/MA/25/000088</p> <p>Acalabrutinib Tablets 100 mg</p> | <p>M/s. AstraZeneca Pharma India Limited.</p> | <p>The firm presented proposal for grant of permission to manufacture and market Acalabrutinib Tablets 100 mg along with CT waiver request for additional indication in combination with bendamustine and rituximab (BR) for the treatment of adult patients with previously untreated mantle cell lymphoma (MCL) before the Committee.</p> <p>The Committee noted that CDSCO already approved Acalabrutinib Capsule/Tablet100mg as second line therapy for the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. Further, the drug is already approved in key countries i.e. US, EU, Japan, Australia and Canada for applied indication.</p> <p>After detailed deliberation, the Committee accepted request for CT waiver and recommended for grant of permission to manufacture and market Acalabrutinib Tablets 100 mg for proposed indication</p> |
| 8) | <p>SND/CT/25/000112</p> <p>Olaparib film coated tablets 100mg and Olaparib film coated tablets 150 mg</p> | <p>M/s. AstraZeneca Pharma India Limited.</p> | <p>The firm did not turn up for the presentation.</p> |