**Recommendations of the SEC (Oncology) made in its 25th meeting held on 18.12.2024 & 19.12.2024 at CDSCO (HQ), New Delhi:**

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| **GCT Division** | | | |
| 1. | CT/17/21<br>Online Submission (35887)<br>INC424 (Ruxolitinib) | M/s Novartis | The firm presented Protocol Amendment Version 06 dated 29 Aug 2024 protocol no. CINC424A2X01B.<br><br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. |
| 2. | CT/136/24<br>Online Submission (46426)<br>1. Datopotamab Deruxtecan (DS-1062a)<br>2. Osimertinib (AZD9291) | M/s Astrazeneca | The firm presented phase 3 clinical study D516NC00001, Version 1.0 dated 04 Dec 2023 and Local CSP - Addendum IND-1, version 1.0 dated 24 Oct 2024.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. |
| 3. | CT/88/24<br>Online Submission (36060)<br>LY3537982 | M/s Eli lily | The firm presented protocol amendment (f) dated 22-Aug- 2024 and Protocol Addendum (6) dated 14-Nov-2024 protocol no. J3M-MC-JZQB.<br><br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. |
| 4. | CT/122/24<br>Online Submission (45486)<br>GIM-122 | M/s CBCC | In light of earlier SEC Recommendation dated 23.10.2024, now the firm presented phase I/II clinical study protocol no. GIM122-CT01 version 3/India 1, 16 September 2024.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. |
| 5. | CT/140/23<br>Online Submission (36191)<br>Nivolumab | M/s Dr. Reddys | The firm presented to Increase the patient numbers from 241 to 265 in India protocol no. NU-01-001.<br><br>After detailed deliberation, the committee recommended for approval of Increase the patient numbers from 241 to 265 in India as presented by the firm. |
| 6. | CT/144/24 46615<br>Online Submission (46615)<br>PF-07220060 100 mg Immediate Release (IR) | M/s Pfizer | The firm presented phase 3 clinical study Protocol no. C4391024 Final Protocol dated 03 September 2024.<br><br>After detailed deliberation, the committee recommended for grant of permission to |

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| | Film- Coated Tablets | | conduct the trial as presented by the firm with following condition<br>1. The number of subjects shall be increased up to 100.<br>2. More government sites shall be included in the study. |
| 7. | CT/41/24 36231 Online Submission (36231)<br>Datopotamab Deruxtecan (DS-1062a) 100mg/vial<br>Rilvegostomig (AZD2936) 750mg/vial (50mg/ml) | M/s AstraZeneca | The firm presented protocol amendment Version 2.0, dated 05 Sep 2024 protocol no. D7632C00001.<br><br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. |
| **Biological Division** | | | |
| 8. | BIO/CT04/FF/2024/45884<br><br>Pembrolizumab 100mg/4mL | M/s Hetero Biopharma Limited | The firm presented the proposal to conduct Phase III study titled "A Prospective, Randomized, Double Blind, Multiple Dose, Multicenter, Active Controlled, Comparative, Parallel Study to Evaluate the Efficacy, Safety, Pharmacokinetic and Immunogenicity of Intravenous Infusion of Hetero-Pembrolizumab (Hetero Biopharma Ltd, India) and Reference Medicinal Product (Pembrolizumab, Merck Sharp & Dohme B.V) in Patients with Non- Squamous Type of Metastatic Non-Small Cell Lung Carcinoma (mNSCLC)" vide Protocol no. HCR/III/PEMBNSCLC/06/2024 Version No. 1.0 dated 16.08.2024.<br>After detailed deliberation, the committee recommended for approval to conduct the Phase III study as per protocol presented by the firm with the following conditions-<br>1. All clinical study investigators should be Medical Oncologist.<br>2.Clinical trial sites should be geographically distributed including Government sites. |

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| 9. | E-46660<br><br>Trastuzumab powder for concentrate for solution for infusion 150mg/vial & 440mg/vial | M/s. Intas Pharmaceuticals Private Limited | The firm presented the CSR of Phase IV study titled "A multicentric, open label, single arm study to evaluate the safety and efficacy of INTP26 (trastuzumab biosimilar)in patients with HER2-overexpressing breast (early & metastatic) cancer or metastatic gastric" conducted vide Protocol no. 0566-18, Version no. 1.1 dated 04.06.2019.<br><br>After detailed deliberation, the committee noted the results of the Phase IV study presented by the firm. |
| 10. | E-27260 & 29382<br><br>Tremelimumab concentrate for solution for infusion 25mg/1.25mL and 300mg/15mL | M/s. AstraZeneca Pharma India Ltd | The firm presented the proposal for update in the package insert for the drug product Tremelimumab Concentrate for Solution for infusion 25mg/1.25mL and 300mg/15mL for updates in the sections of Posology and mode of administration, special warnings and special precautions for use, undesirable effects, Pharmacodynamic properties and Pharmacokinetic properties based on CCDS Version 9.0 dated 17.11.2023.<br><br>After detailed deliberation, the committee recommended for the approval of package insert Version 2.0 dated 04.03.2024 of Tremelimumab Concentrate for Solution for infusion 25mg/1.25mL and 300mg/15mL. |
| **New Drug Division** | | | |
| 11. | ND/IMP/24/000020<br><br>Pyrotinib Maleate tablets 80mg | M/s Dr Reddys Laboratories Limited | In light of earlier recommendations dated 21.08.2024 & 22.08.2024, where the firm was asked to submit the suitable comparative arm as standard of care for further review.<br><br>The firm has presented the Phase III clinical trial protocol before the committee with the standard of care as Trastuzumab and Docetaxel.<br><br>The committee opined that the need for Pertuzumab in combination with Trastuzumab and Docetaxel to be included as standard of care in the protocol. |

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| | | | The committee also opined that the proposed standard of care is recommended as per the global guidance available namely, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO), and European Society for Medical Oncology (ESMO). Also, the committee noted that control arm is inferior to the current global standard of care treatment for HER2+ metastatic breast cancer.<br><br>After detailed deliberation, the committee opined that the control arm should include Pertuzumab in combination with Trastuzumab and Docetaxel.<br><br>Hence, the firm should submit the revised protocol with above standard of care for further review by the committee. |
| 12. | ND-11011(15)/8/2024-eoffice<br><br>Abemaciclib 50mg 100mg, 150mg and 200mg film coated tablets | M/s Eli Lilly and Company | The firm presented the proposal for amendment in Package Insert (PA008SPIN06) for drug Abemaciclib 50mg 100mg, 150mg and 200mg film coated tablets before the committee.<br><br>After detailed deliberation, the committee recommended for grant of approval of amendment in Package Insert (PA008SPIN06) for Abemaciclib 50mg 100mg, 150mg and 200mg film coated tablets as presented by the firm. |
| **SND Division** | | | |
| 13. | SND-12011/12/2024-e-office<br><br>Anastrozole tablet 1 mg | M/s Astrazeneca India Private Limited | The firm presented the proposal for update of prescribing information based on the Company Core Data Sheet of Anastrozole tablets I.P 1mg w.r.t. the following changes:<br>**1. Special warnings and special precautions for use.**<br>**2. Undesirable effects.**<br>**3. Possible side effects.**<br><br>After detailed deliberation, the Committee recommended for grant of approval for the proposed update in prescribing information as presented by the firm. |

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| **Medical Devices Division** | | | |
| 14. | CI/MD/2024/129057 (Cancer Diagnostic Probe) | M/s. Coosa Technologies Private Limited | The proposal of the firm has been re-deliberated by the committee in presence of the Onco-surgeon and Pathologist as decided in the earlier SEC meeting held on 05.12.2024.<br><br>After detailed deliberation, the committee recommended for the grant of permission to conduct proposed Clinical Investigation on the device viz. "Cancer Diagnostic Probe", as per Protocol No AIIMSA2299, Version 1.0 dated 15.08.2024 with the condition that the number of human participants shall be equally enrolled among all the study sites. The applicant shall submit report of the study after its completion for further action in the matter. |