Recommendations of the SEC (Oncology) made in its 02nd/26 meeting held on 21.01.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/173/25 Online Submission (53339) PF-08634404 Concentrate for solution for infusion	M/s. Pfizer Limited	The firm presented phase III clinical study protocol no.: C6461001, Protocol Amendment 2 dated 05-Nov-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1. More geographically distributed government site shall be included in the study. 2. PI shall be Medical Oncologist only. 3. Day care center should not be a part of clinical trial. Dr. Kalyan Kusum Mukherjee didn't participate.
2.	CT/174/25 Online Submission (53345) Surovatamig (AZD0486) concentrate for solution for infusion 16 mg/vial and Surovatamig (AZD0486) powder for solution for infusion 1 mg/vial and 7.5 mg/vial	M/s. AstraZeneca Pharma India Limited	The firm presented phase III clinical study protocol no. D7401C00001 CSP version 5.0 dated 16 October 2025 and Local CSP Addendum IND Version 2.0 dated 31 October 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1. More geographically distributed government site shall be included in the study. 2. PI shall be Medical Oncologist only. 3. Day care center should not be a part of clinical trial.
Biological Division			
3.	BIO/CT04/FF/2025/52309 Pertuzumab concentrate for	M/s. Hetero Biopharma Limited	The firm presented the proposal to conduct Phase I/III clinical trial titled "A Prospective, Randomized, Multicenter, Double Blind, Active Controlled, Parallel Group Study to Compare the

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	solution for Infusion (420 mg/14 mL)		Efficacy, Safety, Pharmacokinetics and Immunogenicity of Hetero-Pertuzumab (Hetero Biopharma Ltd, India) with Reference Medicinal Product (Pertuzumab, Genentech Inc.,) in Combination with Trastuzumab and Docetaxel in Previously Untreated Patients with Human Epidermal Growth Factor Receptor (HER)–2 Positive Metastatic Breast Cancer"; vide Protocol No. HCR/III/PERMBC/08/2025, Version 1.0 dated 29-Aug-2025". After detailed deliberation, the committee recommended grant of permission to conduct the Phase I/III clinical trial as per the presented protocol, subject to the following conditions: 1. All PIs shall be Medical Oncologist. 2. Day care facilities shall not be used as a clinical trial site 3. Clinical trial sites shall be geographically distributed 4. Number of patients shall be proportionate across all the clinical trial sites. 5. Post-trial access of the study drug shall be provided to the subjects till disease progression. **Note:** Dr. Kaushal Kalra did not participate in the deliberation.
4.	BIO/CT18/FF/2025/51116 Serplulimab Concentrate for Solution for Infusion 100 mg/10 ml Vial (10 mg/ ml) (r-DNA origin)	M/s. Intas Pharmaceuticals Ltd	The firm presented a proposal for grant of approval of following additional indications of Serplulimab Concentrate for Solution for Infusion 100 mg/10 ml Vial (10 mg/ml) (r-DNA origin) with a request for local clinical trial waiver. **Squamous Non-small cell lung carcinoma (Sq-NSCLC):** Serplulimab in combination with carboplatin and nab-paclitaxel is indicated for the first-line treatment of adult patients with unresectable, locally advanced or metastatic squamous non-small cell lung (NSCLC) carcinoma. **Non-Squamous Non-small cell lung carcinoma (Nsq-NSCLC):** Serplulimab

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			in combination with carboplatin and pemetrexed is indicated for the first-line treatment of adult patients with locally advanced or metastatic non-squamous non-small cell lung carcinoma who do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) positive mutations. **Oesophageal squamous cell carcinoma (ESCC):** Serplulimab in combination with fluoropyrimidine- and platinum-based chemotherapy is indicated for the first-line treatment of adult patients with unresectable, locally advanced/recurrent or metastatic oesophageal squamous cell carcinoma whose tumours express PD-L1 with a CPS≥ 1. The committee noted that firm has not conducted local clinical trials in the country and does not qualify for consideration of a clinical trial waiver under Rule 101 of the NDCT Rules, 2019. After detailed deliberation, the committee recommended that the proposal of firm for grant of aforesaid additional indications may not be considered at this stage.
5.	BIO/CT04/FF/2025/51719 Daratumumab Concentrate for Solution for Infusion (100 mg/5 mL and 400 mg/20 mL)	M/s. Intas Pharmaceuticals Ltd	The firm presented a proposal to conduct a Phase I/III clinical trial titled, A Prospective, Randomized, Double - Blind, Active - Controlled, Multi - Centre, Three - Arm Study to Investigate Pharmacokinetics, Efficacy, Safety and Immunogenicity of Intas Daratumumab (INTP33) Compared to DARZALEX® in Patients with Relapsed or Refractory Multiple Myeloma.″ vide Protocol No.: 0165-25, Version No.: 1.0, Dated 03-Jul-2025 meant for USFDA and EMA submission only. After detailed deliberation, the committee recommended for grant of permission to conduct Phase I/III clinical trial as per the protocol presented by the firm subject to following conditions: 1. All PIs shall be Medical

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			Oncologist or Haematologist. 2. Day care facilities shall not be used as a clinical trial site. 3. Clinical trial sites shall be geographically distributed. 4. Number of patients shall be proportionate between government and private clinical trial sites. 5. Post-trial access of the study drug shall be provided to the subjects till disease progression. 6. The firm is required to submit undertaking that the data generated on the basis of this study is for registration in foreign country and shall not be claimed for registration in India.
New Drug Division			
6.	ND/CT/24/000085 Gilteritinib 40 mg Tablets	M/s. Astellas Pharma India Pvt. Ltd.	The firm presented PMS study protocol (Protocol no. ISN/Protocol 2215-MA-3635, Version 1.0 dated 27-Sep-2024) for the drug Gilteritinib 40 mg Tablets, before the committee. After detailed deliberation, the committee recommended for the grant of permission to conduct active PMS study for Gilteritinib 40 mg Tablets subject to condition that the firm should to conduct PMS study in at least 35 patients. Further the committee noted that firm is providing the drug free of the cost in Active PMS study and recommended that the firm should also give Post-trial access of the drug to patients till progression of disease. Accordingly, the firm should submit the revised PMS study protocol to CDSCO.
SND Division			
7.	SND/CT/25/000151 Enzalutamide 32 mg/mL oral solution	M/s. BDR Pharmaceuticals International Pvt. Ltd.	Firm presented proposal for grant of permission to conduct Phase IV Clinical Trial protocol before the committee. After detailed deliberation, the committee

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			recommended for grant of permission to conduct of Phase IV Clinical Trial study as per the protocol presented by the firm with the following conditions- 1) Study duration should be increased to one year and subsequent follow-up duration should be increased to one year after completion of the study. 2) Interim report should be submitted every 6 months. 3) Only qualified Medical Oncologists should be Principal Investigator. 4) Post-trial access should be provided to all the patients. 5) 50% of the Clinical Trial study centers should be Government sites and Clinical Trial study centers should be geographically distributed. Daycare facility should not be Clinical trial site.
8.	SND/CT/2025/00014 1 SND/CT04/FF/2025/5 3647 Osimertinib tablets 40 mg/80 mg.	M/s. AstraZeneca Pharma India Limited	Firm presented proposal for grant of permission to conduct Phase IV Clinical Trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct of Phase IV Clinical Trial study as per the protocol presented by the firm with the following conditions- 1) Only qualified Medical Oncologists should be Principal Investigator. 2) Post-trial access should be provided to all the patients. 3) 50% of the Clinical Trial study centers should be Government sites and Clinical Trial study centers should be geographically distributed. Daycare facility should not be Clinical trial site.