Recommendations of the SEC (Oncology) made in its 08th/26 meeting held on 10.03.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/20/26 Online Submission (54844) Sonesitatug -Vedotin, (AZD0901), Lyophilisate for Concentrate for solution for infusion (50 mg/vial) Rilvegostomig (AZD2936), Concentrate for solution for Infusion 750 mg/vial (50 mg/mL)	M/s. AstraZeneca Pharma India Limited	The firm presented phase III clinical study protocol no. D9803C00001 version no. 2.0 dated 28-NOV-2025 and Local CSP – Addendum 2.0 India, Version 1.0 dated 08-Dec-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.
BABE Division			
2.	BABE/CT05/FF/2025/53980 Lorlatinib Film-Coated Tablets 100 mg	M/s. Jeevan Scientific Technology Limited	Firm presented the BA/BE study Protocol No. 25-289 Version No. 01 Protocol Date 26-DEC-2025 for export purpose only, before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BABE study for export purpose only, subject to condition that the firm shall include an additional safety monitoring and follow-up of the study subjects up to six (6) month.
Biological Division			
3.	BIO/CT04/FF/2025/49684 INTP58 (Intas Pembrolizumab Solution for Injection 100 mg/4 mL Vial (25 mg/ml))	M/s. Intas Pharmaceuticals Ltd.	In light of earlier recommendation of SEC (Oncology) dated 28.08.2025, the firm presented revised protocol to conduct a Phase I/III clinical trial titled "Phase-1/3, Randomized, Assessor-Blind, Active-Controlled, Parallel, Two Arm, Multicentre Study, to Compare Efficacy, Safety, Pharmacokinetics, and Immunogenicity of INTP58 versus Keytruda, Both Administered with Platinum-Doublet Chemotherapy, in the First-Line Treatment of Patients with Locally-Advanced or Metastatic Squamous or Non-Squamous Non-Small Cell Lung Cancer." as per Protocol No.

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			0142-25, Version 2.1, dated 18 October 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I/III clinical trial as per the presented protocol subject to following conditions: 1. All PIs should be Medical Oncologist. 2. Day care facilities should not be used as a clinical trial site. 3. Clinical trial sites should 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 until disease progression.
4.	BIO/CT04/FF/2025/498 69 Nivolumab Injection 100 mg/10 mL vial	M/s. Enzene Biosciences Ltd.	In light of earlier recommendation of SEC (Oncology) dated 23.12.2025, the firm presented a revised protocol for grant of approval 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 3.0, dated 29 Jan 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as per the protocol presented by the firm.
New Drugs Division			
5.	ND/CT/25/000071 Nelarabine Injection 250 mg/50 ml (5 mg/ml)	M/s. MSN Laboratories Private Limited	In light of earlier recommendation dated 14.11.2025, the firm presented revised Phase IV clinical trial protocol (Protocol no. 014/NLRN/MSN/2025, Version no.: 2.0, Dated: 09 Jan 2026) before the committee.

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			After detailed deliberation, committee recommended for grant of permission to conduct Phase IV clinical trial as per the revised protocol presented by the firm.
6.	ND/CT/25/000092 Tucatinib Tablets 150 mg	M/s. BDR Pharmaceuticals International Pvt Ltd	In line with the condition of permission for manufacture and market of the drug, Tucatinib Tablets 150 mg, the firm presented Phase IV clinical trial protocol (Protocol No.: SLS-CT-0003-25-TUCA, Version No.: 04, Date: 09 Mar 2026) before the committee. After detailed deliberation, committee recommended for grant of permission to conduct Phase IV clinical trial as per the protocol presented by the firm with following condition: 1) All the Principle Investigator's shall be Medical Oncologist only. 2) Day care center should not be part of clinical trial site. 3) Clinical trial sites shall be geographically distributed.
SND Division			
7.	SND/MA/25/000172 Temozolomide Oral Suspension 30 mg/ml	M/s. Zydus Lifesciences Limited	The firm presented the proposal for grant of permission for manufacture and market Temozolomide Oral Suspension 30 mg/ml (additional dosage form) along with justification for BE study & Phase III clinical trial study waiver before the committee. After detailed deliberation, the committee recommended that, firm should conduct Bioequivalence study to establish the equivalency of proposed dosage form with already approved formulation. Accordingly, firm should submit the protocol to conduct the Bioequivalence study and also required to submit the study data for the palatability of the proposed formulation in the special population such as pediatrics and Geriatrics for further consideration.
8.	SND/IMP/26/000009 Lenvatinib Capsules IP 4 mg /10 mg	M/s. Eisai Pharmaceuticals India Private Limited	Firm presented the proposal for grant of permission to Import and market Lenvatinib Capsules IP 4 mg / 10 mg for the additional indication for the treatment of unresectable thymic carcinoma with

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			justification for waiver of Local Phase-III clinical trial and Phase-IV clinical trial. The committee noted that Lenvatinib Capsules IP 4 mg / 10 mg is approved for the applied indication in Japan and unresectable thymic carcinoma is a rare condition and there is an unmet medical need. After detailed deliberation, the committee recommended for grant of permission for import and marketing of Lenvatinib Capsules IP 4 mg / 10 mg for the applied indication for the treatment of unresectable thymic carcinoma subject to condition that the firm should conduct Phase-IV clinical trial. Accordingly, the firm should submit Phase-IV clinical trial protocol to CDSCO within 03 months from date of approval of the drug product for review by the committee