Recommendations of the SEC (Oncology) made in its 23rd/26 meeting held on 09.09.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/129/26 Online Submission (58582) Rinzimetostat	M/s. ICON Clinical Research India Private Limited.	The firm presented phase III clinical study protocol no: ORIC-944-05, version no. 1 dated 21-MAY-2026. After detailed deliberation, the committee opined that the firm shall submit safety data from Phase I and Phase II clinical studies and pre-clinical study data to CDSCO for further review by the Committee.
Biological Division			
2.	E- 122747 & 132635 Trastuzumab deruxtecan powder for concentrate for solution for infusion 100 mg (Enhertu)	M/s. Astra Zeneca Pharma India Limited.	The firm presented the proposal for update in Package Insert for the drug product Trastuzumab deruxtecan powder for concentrate for solution for infusion 100 mg (r-DNA Origin) in pre-filled pen (Ozempic®) incorporating safety updates from DESTINY- Gastric 04 and DESTINY - Gastric-06 clinical trials. After detailed deliberation, the committee recommended for approval of proposed updates in the package insert of the said drug product.
3.	E- 138842 Elranatamab solution for injection 44mg/1.1 mL (40mg/mL) and 76mg/1.9mL (40mg/mL) (r-DNA origin)	M/s. Pfizer Products India Private Limited.	The firm did not attend the meeting.
4.	BIO/CT18/FF/2025/48930 Toripalimab Injection 240mg/6mL (r-DNA origin)	M/s. Dr. Reddy's Laboratories Limited	In light of earlier recommendations of SEC (Oncology) dated 29-07-2025, the firm presented the proposal for grant of approval of additional indication for Toripalimab Injection 240 mg/6 mL i.e. "Toripalimab in combination with cisplatin and paclitaxel for the first line treatment of adult patients with unresectable advanced, recurrent, or metastatic Esophageal squamous cell carcinoma" based on the results of Phase IV Clinical Trial of Toripalimab Injection 240 mg/ 6 mL conducted in Indian Patients with Recurrent or Metastatic Nasopharyngeal Carcinoma and global clinical studies conducted by the firm for the proposed

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			indication. After detailed deliberation, the committee recommended for the grant of approval for the proposed additional indication, in line with the EMA approval, subject to the condition that firm shall conduct the Phase-IV clinical trial in India for the proposed indication of ESCC. Accordingly, the protocol to conduct the Phase IV study shall be submitted within three months of grant of marketing authorization permission.
5.	BIO/CT21/FF/2026/56469 Nivolumab 120 mg/12 mL, concentrate for solution for infusion, single dose vial	M/s. Dr. Reddy's Laboratories Limited.	The firm presented the proposal for the grant of approval of additional presentation of 120mg/12mL of already approved drug product Nivolumab concentrate for solution for infusion, single dose vial. The committee noted that same presentation is approved by EMA and USFDA for the innovator product. After detailed deliberation, the committee recommended for the grant of approval for the proposed additional presentation of 120mg/12mL for Nivolumab concentrate for solution for infusion, in line with the EMA and USFDA approval.
6.	BIO/CT04/FF/2026/56524 Durvalumab Solution for Infusion 120 mg/2.4 mL and 500 mg/10 mL	M/s. AstraZeneca Pharma India Limited.	The firm presented the proposal to conduct a Phase IV clinical trial titled- "A prospective, multi-center, phase 4, single arm study to assess the safety of neoadjuvant-adjuvant durvalumab and FLOT chemotherapy followed by adjuvant durvalumab in Indian patients with resectable Gastric and Gastro esophageal Junction Adenocarcinoma (GC/GEJC)" vide protocol no. D4191L00176; Version No.01 dated 23-Apr-2026. After detailed deliberation, the committee recommended for the grant of permission to conduct the proposed Phase IV trial 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 with

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			proportionate number of Government sites. 4. Sample size of the study should be increased to minimum 100 evaluable subjects.
7.	BIO/CT21/FF/2026/56695 Nivolumab 20 mg/2 mL, concentrate for solution for infusion, single dose vial	M/s. Dr. Reddy's Laboratories Limited.	The firm presented the proposal for the grant of approval of additional presentation of 20mg/2mL of already approved drug product Nivolumab concentrate for solution for infusion, single dose vial. The Committee noted that there is no usability of proposed presentation with lower content of drug in the vial i.e. 20mg per 2mL vial in the adult population. The committee further noted that the proposed presentation is not approved in USFDA and EMA for the innovator product. After detailed deliberation, the committee did not consider firm's proposal for addition of lower presentation of 20mg/2mL of the said drug product.
SND Division			
8.	SND/CT/25/000151 Enzalutamide oral solution 32 mg/mL	M/s. BDR Pharmaceuticals International Pvt. Ltd.	In light of earlier SEC recommendation dated 21.01.2026, firm presented revised Phase IV Clinical Trial protocol before the Committee. After detailed deliberation, the Committee recommended approval of the amended protocol to conduct Phase IV Clinical Trial Study as presented by the firm.