Recommendations of the SEC (Oncology) made in its 02nd /25 meeting held on 16.01.25 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/123/24 Online Submission (45756) OX-4224(Evixapodlin)	M/s Klinera Global Services	The firm presented phase 2 clinical trial protocol no. OX-4224-200 version 1.0 dated 31 August 2024 After detailed deliberation, the committee opined that the firm shall submit the revised protocol with respect to following for further review by the committee: 1. Define the rationale in the protocol for selection of 500 mg or 1000mg dose 2. Define the end-points whether for safety or efficacy to detect the difference between the two dose in protocol 3. Adequate sample size to meet the primary end-points once defined
2.	CT/55/21 Online Submission (36263) JNJ-17000139 Gemcitabine 225 mg Intravesical delivery system (TAR-200) JNJ-63723283 (Cetrelimab)	M/s Pharmaceuticals Research Associates India Private Limited	The firm presented protocol amendment 5 dated 16 October 2024 protocol no. 17000139BLC3001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/105/22 Online Submission (36369 FDC of Pertuzumab+ Trastuzumab for SC (PH FDC SC) RO7198574) And Giredestrant (RO7197597)	M/s Roche	The firm presented protocol amendment 5 dated 02 October 2024 protocol no. WO43571. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/123/23 Online Submission (36438) Giredestrant	M/s Roche	The firm presented protocol amendment version 3.0 dated 06 Sep 2024 protocol no. CO44657. After detailed deliberation, the committee

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			recommended for approval of protocol amendment as presented by the firm.
5.	CT/73/23 Online Submission (36610) Pembrolizumab 200 mg + Vibostolimab	M/s MSD	The firm didn't turn up for presentation.
Biological Division			
6.	BIO/CT18/FF/2024/45144 Tislelizumab Injection 100mg (10ml)/Vial	M/s. Glenmark Pharmaceutical Ltd.	In light of the earlier SEC recommendations dated 06.11.2024, the firm presented the safety and efficacy data of 28 Indian patients in Non-small cell lung cancer (NSCLC) and head neck squamous cell cancer (HNSCC) participated in the Global Clinical Trial (GCT). The Committee noted that the drug is approved in USA, Europe, United Kingdom, Australia, China and other countries. The committee noted that the proposed indications comes under the category of Orphan Drug and there is an unmet medical need in the country. After detailed deliberation, the committee recommended for the grant of permission to import and market the drug with waiver of local clinical trial with condition to conduct Phase-IV clinical trial in India for both the proposed indications. Accordingly, firm shall submit Phase IV Clinical Trial protocol to CDSCO within 03 months of grant of marketing authorization.
7.	BIO/CT18/FF/2023/40741 Durvalumab solution for infusion 120mg /2.4ml and 500 mg/10ml	M/s. AstraZeneca Pharma India Limited	In light of the earlier SEC recommendations dated 03.04.2024 & 04.04.2024, wherein the committee has recommended for approval of the additional indication "Durvalumab in combination with Tremelimumab, is indicated for the treatment of patients with unresectable hepatocellular carcinoma (uHCC) by including as first line therapy for Child Pugh Class A patients in the applied indication".

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			The firm has presented the justification for not including the wording "as first line therapy for Child Pugh Class A patients" in the applied indication as recommended by SEC on 03.04.2024 & 04.04.2024. The committee noted that for the drug Tremelimumab the same indication is approved as combination therapy i.e., "Tremelimumab in combination with Durvalumab is indicated for the treatment of patients with unresectable hepatocellular carcinoma (uHCC)". After detailed deliberation, the committee recommended for approval of the proposed indication as requested by the firm i.e., Durvalumab in combination with Tremelimumab is indicated for the treatment of patients with unresectable hepatocellular carcinoma (uHCC).
BA/BE Division			
8.	BABE/CT05/FF/2024 /45283 Netupitant and Palonosetron hydrochloride injection for intravenous use (197.5 mg / 0.28 mg per 100 mL)	M/s Veeda Clinical Research Limited	The firm presented the Protocol No. 24-VIN-0375, Version No. 01, Protocol Date 30-AUG-2024. After detailed deliberation, the committee recommended for grant of permission for the conduct of the BABE study for export purpose only.