Recommendations of the SEC (Oncology) made in its 22st meeting held on 06.11.2024 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	GCT/CT04/FF/2024/42731 Online Submission (42731) FYB206 (Pembrolizumab)	M/s. InVentiv International Pharma services Pvt. Ltd	In light of earlier SEC Recommendation dated 07.08.2024 and 08.08.2024, now the firm presented Phase III clinical study protocol no. FYB206-C3-02, amendment 1, version 2.0 dated 22 February 2024. After detailed deliberation, the committee opined that as phase-I study is already Being conducted outside India, PK data shall be submitted by the firm for further review by the committee.
2.	GCT/PostAppr/2024/33670 Online Submission (33670) Pacritinib (SB 1518)	M/s PSI CRO	The firm presented protocol amendment 11 version 4.0 dated 23 May 2024 protocol no. PAC 303. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
3.	BIO/CT18/FF/2024/44944 Polatuzumab Vedotin for Injection 30mg per vial	M/s. Roche Products (India) Private Limited	The firm presented the proposal for grant of approval of additional indication of Diffuse large B-cell lymphoma (r/r DLBCL) for the already approved drug Polatuzumab Vedotin for injection (Polivy) 30mg/vial. The committee noted that the proposed indication is already approved for the other pack presentation i.e 140mg/mL of the same drug and there is no change in the approved strength of the drug. After detailed deliberation, the committee recommended for grant of approval of additional indication for the pack presentation of Polatuzumab Vedotin for injection (Polivy) 30mg/vial with the condition of the initial approval of Polatuzumab Vedotin (Polivy) 140 mg/vial for Injection i.e., "The drug should be prescribed only for the patients who are not eligible for transplant procedure as certified by tumor board of the hospital".

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			Accordingly, revised PI shall be submitted to CDSCO.
4.	BIO/CT18/FF/2024/44442 Nivolumab 40mg/4mL, 100mg/10mL, 240mg/24mL in a single dose vial	M/s. BMS India Pvt. Ltd.	The firm presented the proposal for the approval of additional indication for the drug Nivolumab 10mg/ml concentrate for solution for infusion i.e. "Nivolumab in combination with cisplatin and gemcitabine, is indicated for the first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma" with local clinical trial waiver. The firm presented the safety and efficacy data from the global clinical studies where India is not a part of the study. The committee noted that the proposed indication of the drug is approved in USA, Europe, United Kingdom, Canada and Brazil. After detailed deliberation, the committee recommended for approval of additional indication of Nivolumab 10mg/ml concentrate for solution for infusion i.e. "Nivolumab in combination with cisplatin and gemcitabine, is indicated for the first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma" with a waiver of local Phase III clinical trial and with the condition that firm is required to conduct Phase IV clinical trial in Indian population for the proposed indication. Accordingly, the protocol to conduct the Phase IV study shall be submitted within 3 months of grant of permission of additional indication.
5.	BIO/CT18/FF/2024/45144 Tislelizumab injection 100 mg (10ml/vial)	M/s Glenmark Pharmaceuticals Ltd	The firm presented the proposal for grant of permission to import & market Tislelizumab Injection 100mg (10ml)/Vial in India for the indication of ESCC and NSCLC with waiver of local clinical trial. The firm presented the safety and efficacy data from various global clinical

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			studies in the proposed indications. The meta data of safety and efficacy in comparison with other approved monoclonal antibodies was also deliberated. The committee noted that drug is approved in USA, Europe, United Kingdom, Australia, China and other countries. The committee noted that safety and efficacy data is not available in Indian patients. The committee also examined the proposal in light of Rule 101 under NDCT Rules 2019 and order issued by the Directorate dated 07.08.2024 for waiver of clinical trial in India. After detailed deliberation the committee recommended that firm should submit the safety and efficacy data of Indian patients.
6.	BIO/CT04/FF/2024/45046 Nivolumab 10mg/ml solution for intravenous infusion	M/s Lupin Limited	The firm presented the protocol for the conduct of Phase III clinical trial titled "A randomized, double-blind, multi-center, active-control, parallel group study to compare efficacy, safety, immunogenicity and pharmacokinetics of Lupin's Nivolumab (LUBT022) with Innovator's Nivolumab in patients with locally advanced or metastatic non-small cell lung cancer" vide Protocol no. LRP/LUBT022/2024/002, Version 1.0 Dated 14.08.2024. After detailed deliberation, the committee recommended for conduct of Phase III study as per presented protocol with the following conditions- 1. Principal Investigator must be a medical oncologist. 2. The trial sites should be geographically distributed with 50% of Government sites. 3. Minimum number of evaluable patients should be 100 in test arm. Accordingly, the firm should submit revised protocol to CDSCO for further evaluation.
7.	BIO/CT21/BO/2024/45000	Ms. Intas Pharmaceuticals	The firm presented the proposal for grant of approval to manufacture and market

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Pertuzumab concentrate for Solution for Infusion 420 mg/14 mL Vial	Ltd.	Pertuzumab concentrate for Solution for Infusion 420 mg/14 mL Vial for the indications of HER2-positive Metastatic Breast Cancer and HER2-positive Early Breast Cancer based on the results of Phase III clinical trial. After detailed deliberation, the committee recommended for the grant of approval to manufacture and market Pertuzumab concentrate for Solution for Infusion 420 mg/14 mL Vial for the indication of HER2-positive Metastatic Breast Cancer only with the condition that firm shall conduct Phase IV study in the country. Accordingly, the protocol to conduct the Phase IV study shall be submitted within 3 months of grant of marketing authorization permission to manufacture and market the drug product.
New Drugs Division			
8.	ND-11011(15)/ 15/2024-eoffice Entrectinib Capsules 100mg/200mg	M/s Roche	The firm did not turn up for the presentation