Recommendations of the SEC (Oncology) made in its 24th/25 meeting held on 29.07.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/49/24 Online Submission (39786) Acalabrutinib Capsules	M/s. Fortrea Development India Private Limited	The firm presented protocol amendment version 9.0 dated 29 April 2025 protocol no. ACE-LY-312 (D8227C00001). After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/25/24 Online Submission (39877) ALT-803	M/s. CBCC Global Research LLP	The firm presented protocol amendment version 15 dated 21 March 2025 protocol no. CA-ALT-803-01-14; QUILT T-2.005. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/44/21 Online Submission (39945) Atezolizumab Injection 1200 mg/20 ml	M/s. Roche Products (India) Private Limited	The firm presented protocol amendment version 6.0 dated 05 Feb 2025 protocol no. WO42633. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/83/25 Online Submission (50214) QL2107 Injection	M/s. Syneos Health India Private Limited	The firm presented phase III clinical study protocol no. QL2107-102, version 1.0 dated 03 March 2025. After detailed deliberation, the committee opined that the proposed clinical trial is focused completely on Pharmacokinetic (pK) parameters. Moreover, primary objective and secondary objective of phase-III study protocol has not been demonstrated for confirmation of therapeutic benefit and efficacy end point. Hence, the committee didn't recommend to conduct the clinical trial in India.
5.	CT/84/25 Online Submission (50220) Lisaftoclax	M/s. IQVIA RDS (India) Private Limited	The firm presented phase III clinical study protocol no. APG2575CC301 version no. 2.0 dated 15 April 2025. After detailed deliberation, the committee

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	(APG-2575)		opined that the firm shall submit phase I & II study report including safety data, global approval status of the drug with indication, prescribing information…etc. for further review by the committee.
6.	CT/85/25 Online Submission (50243) Lisaftoclax (APG-2575)	M/s. IQVIA RDS (India) Private Limited	The firm presented phase III clinical study protocol no. APG2575AG301 version no. 1.2 (EU) dated 16 April 2025. After detailed deliberation, the committee opined that the firm shall submit phase I & II study report including safety data, global approval status of the drug with indication, prescribing information…etc. for further review by the committee.
Biological Division			
7.	BIO/CT21/FF/2025/48853 Pertuzumab Concentrate for Solution for Infusion 420 mg/14 mL Vial (30 mg/mL)	M/s. INTAS PHARMACEUTICALS LTD	The firm presented the proposal for grant of approval of additional indication of HER2 positive Early Breast Cancer for the drug product Pertuzumab concentrate for solution for infusion 420 mg/ 14 mL vial (30 mg/ mL) based on the extrapolation of indication. After detailed deliberation, the committee recommended for the grant of permission for the proposed additional indication subject to the condition that firm should include adequate number of patients of HER2 positive Early Breast Cancer in the Phase IV trial in India.
8.	BIO/CT04/FF/2025/49028 Pertuzumab Concentrate for Solution for Infusion 420 mg/14 mL Vial (30 mg/mL)	M/s. INTAS PHARMACEUTICALS LTD	The firm presented the proposal for grant of permission to conduct a Phase IV study titled "A Single-Arm, Non-Randomised, Interventional, Post-Approval Phase-4 study to investigate safety, Immunogenicity and efficacy with Pertuzumab Intravenous injection in Female participants with HER2- Positive Breast Cancer" vide Protocol No. 0141-25, Version: 1.0 dated 17-Apr-2025. After detailed deliberation, the committee recommended for approval to conduct the Phase IV clinical trial subject to the

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			following conditions- 1. Number of cycles to be increased for the patients who are responding to the treatment at least for one year in Early Breast Cancer and till progression in Metastatic Breast Cancer. 2. Sample size should be increased considering the different settings of treatment of Metastatic and Early Breast Cancer and the number of patients in each cohort should be atleast 70. 3. All PIs should be Medical Oncologist and more number of geographically distributed sites including proportional Government sites should be included in the study. Accordingly, firm should submit revised protocol to CDSCO for further evaluation.
9.	BIO/CT04/FF/2025/49114 Nivolumab Concentrate for Solution for Infusion 100 mg/10 mL Vial (10 mg/mL)	M/s. INTAS PHARMACEUTICALS LTD	The firm presented the proposal for grant of permission to conduct a Phase I/III study titled "A Phase 1/3, Randomized, Multicentre, Assessor-Blind, Two-Arm, Parallel-Group, Comparative Clinical study to Investigate the efficacy, Immunogenicity, Safety and Pharmacokinetics of Intas Nivolumab Versus" vide Protocol No. 0139, Version: 1.1 dated 16-Apr-2025 After detailed deliberation, the committee recommended for following changes in the protocol- 1. Statistical calculation of sample size should be recalculated considering narrowed Non inferiority margin. 2. Quality of life should be one of the study endpoint. 3. Analysis of PK data of initially

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			dosed patients should be part of protocol design to test the futility of the trial. 4. All PIs should be Medical Oncologist and more number of geographically distributed sites including proportional Government sites should be included in the study. Accordingly, firm should submit revised protocol to CDSCO for further evaluation by the Committee.
10.	BIO/CT18/FF/2025/48930 Toripalimab Injection 240 mg/6 mL (r-DNA origin)	Dr. Reddy's Laboratories Limited	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 global clinical studies conducted by the firm for the proposed indication. The committee noted that Phase IV clinical trial of Toripalimab Injection 240 mg/ 6 mL in India is ongoing and at present complete safety data of Indian population is not available. After detailed deliberation, the committee recommended the firm to submit the complete results of ongoing Phase IV study for further consideration.