

Recommendations of the SEC (Oncology) made in its 23th meeting held on 05.12.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/40/24 Online Submission (42322) Pembrolizumab (BAT3306)	M/s IQVIA	In light of earlier SEC Recommendation dated 08.10.2024 and 09.10.2024, now the firm presented phase I/III clinical study protocol no:BAT-3306-002-CR, Version: 1.0, dated 19 Dec 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/68/24 Online Submission (43277) MK-1084	M/s MSD	In light of earlier SEC Recommendation dated 09.07.2024, now the firm presented phase 3 clinical study protocol no. MK-1084-004 version 00 dated 15 December 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1. The number of subjects shall be increased up to 50. 2. More Geographically distributed government sites shall be included in the study.
3.	CT/151/23 33716 Online Submission (33716) AZD5305	M/s AstraZeneca	The firm presented protocol amendment version 4.0 dated 23 May 2024 protocol no. D9723C00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/128/24 46095 Online Submission (46095) Nivolumab and Relatlimab	M/s BMS	The firm presented phase 3 clinical study protocol no. CA224-1093 version 2.0 dated 20 June 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1. The number of subjects shall be increased up to 100. 2. More geographically distributed government sites shall be included in the study. 3. PI shall be Medical oncologist only.

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Biological Division			
5.	BIO/CT18/FF/2024/4 5384 Durvalumab Solution for infusion 120mg/2.4mL and 500mg/10mL	M/s. Astra Zeneca Pharma India Limited	The firm did not turn up for the presentation.
6.	BIO/CT04/FF/2024/4 5840 Pertuzumab Concentrate for solution for Infusion 420 mg/14 mL	M/s. Zydus Lifesciences Limited	<p>The firm presented the proposal to conduct the Phase IV study titled “A Phase 4, Prospective, Multicenter, Single-Arm Study to Evaluate the Safety of Pertuzumab (Sigrima™, Zydus Lifesciences Limited) in Patients with HER2-Positive Metastatic and Early Breast Cancer.” vide Protocol No: PERT.24.001 Version 01 dated 03.10.2024.</p> <p>After detailed deliberation the committee recommended for approval to conduct the Phase IV study with following changes in the protocol-</p> <ol style="list-style-type: none"> 1. Number of cycles to be increased for the patients who are responding to the treatment of 6 cycles in adjuvant and metastatic cancer settings atleast for one year. 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 cancer setting should be proportionate. 3. PI should be Medical Oncologist. <p>Accordingly, firm should submit revised protocol to CDSCO for further evaluation.</p>
7.	E-45337 Durvalumab Solution for infusion 120mg/2.4mL and 500mg/10mL	M/s. Astra Zeneca Pharma India Limited	<p>The firm presented the final Clinical Study Report (CSR) Version 1.0 dated 28-Jun-2024 for the Phase IV clinical study titled “A prospective, multicenter, Phase-IV clinical trial to assess the safety of Durvalumab in Indian adult patients with locally advanced, unresectable non-small cell lung cancer (NSCLC)” conducted by firm.</p> <p>After detailed deliberation, the committee noted the results of Phase</p>

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			IV study presented by the firm.
Medical Device Division			
8.	CI/MD/2024/129057 (Cancer Diagnostic Probe)	M/s. Coosa Technologies Private Limited	<p>The firm presented the proposal for grant of permission to conduct Pilot Clinical Investigation of the proposed product Cancer Diagnostic Probe on Indian population.</p> <p>After detailed deliberation, the committee opined that the said proposal may be discussed in presence of Oncology Surgeon and Pathologist before taking necessary action in the matter.</p>
New Drugs Division			
9.	ND/IMP/24/000074 Zanubrutinib Capsules 80mg	M/s Glenmark Pharmaceuticals Ltd.	<p>The firm presented the proposal for import and marketing of the drug, Zanubrutinib Capsules 80mg along with justification of local Phase-III clinical trial waiver before the committee. The firm presented the global clinical data for safety and efficacy of drug.</p> <p>The committee deliberated in detail on unmet medical need along with long-term studies on progression free survival. The committee noted that the drug falls under unmet medical need. The committee agreed for local Phase III CT waiver.</p> <p>The committee noted that the drug is approved in 72 countries including US, Australia, Canada, EU and UK.</p> <p>After detailed deliberation, the committee recommended for grant of permission to import and market the drug, Zanubrutinib Capsules 80mg with local Phase III Clinical trial waiver with the condition to conduct structured Phase-IV Clinical Trial in which all five indications are included. The firm is required to submit Phase-IV study protocol to the CDSCO within the period of three months of approval of the drug for further review by the committee.</p>