

Recommendations of the SEC (Oncology) made in its 09th/25 _{meeting held on 20.03.2025 at CDSCO (HQ), New Delhi:}

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/143/21 Online Submission (37605) Hydrogen Peroxide	M/s IQVIA RDS India Pvt. Ltd	The firm presented protocol amendment version 5.0 dated 20 Dec 2024 protocol no. CCR5119. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/47/24 Online Submission (37611) AZD0901 Powder for Solution for Infusion	M/s Astrazeneca Pharma India Limited	The firm presented protocol Amendment version 2.0 dated 20 Aug 2024 protocol no. D9802C00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/16/25 Online Submission (47853) Pembrolizumab/QL21 07	M/s Synoes Health India Private Limited	The firm presented phase III clinical study protocol no. QL2107-301 version 1.0 dated 15-November-2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. Dr. Kaushal Kalra didn't participate.
4.	CT/15/25 Online Submission (47870) LY3537982	M/s Clinical trials Eli lily and Company India Pvt. Ltd	The firm presented phase III clinical study Protocol no. J3M-MC-JZQH version no. Initial protocol dated 13-NOV-2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1 More geographically distributed government sites shall be included in the study. 2. PI shall be Medical Oncologist only. 3. Number of subjects shall be Increased upto 50.
Biological Division			

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5.	BIO/CT21/BO/2024/4 6864 Pertuzumab 30mg/mL solution for infusion	M/s Enzene Biosciences Ltd	<p>The firm presented the proposal for grant of permission to manufacture and market Pertuzumab 420mg/14mL concentrate for solution for infusion for the indications of HER2-positive Metastatic Breast Cancer and HER2-positive Early Breast Cancer based on the results of the Phase III clinical trial conducted in India.</p> <p>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.</p> <p>Accordingly, the protocol to conduct the Phase IV study shall be submitted to CDSCO within 3 months of grant of marketing authorization permission to manufacture and market the drug product.</p>
6.	BIO/CT04/FF/2024/4 6815 Nivolumab 10mg/ml	M/s Reliance Life Sciences Pvt Ltd	<p>The firm presented the protocol to conduct Phase I/III clinical trial titled "A Prospective, Multicenter, Randomized, Double-Blind, Parallel-Group, Two-Arm Comparative Phase I/III Clinical Study to Evaluate the Efficacy, Safety, Pharmacokinetics and Immunogenicity of R-TPR-067 (RLS-Nivolumab) and Opdivo®/ Opdyta® administered by intravenous route in Patients previously treated for Locally Advanced or Metastatic Non-Small Cell Lung Cancer vide Protocol No.: RLS/ONC/2024/05 Version 1.0, Dated 18 Oct 2024.</p> <p>After detailed deliberation, the committee recommended the following:</p> <ol style="list-style-type: none"> 1. Assumptions of the Statistical calculations of sample size and Equivalence margin should be reevaluated to give acceptable results at the lower margin of overall response rate (ORR) 2. More number of study sites to be included. 3. All PI should be Medical Oncologist.

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			Accordingly, the firm should submit revised protocol to CDSCO for further evaluation by the committee. NOTE: Dr. Kalyan Mukherjee did not participate in the discussion
New Drug Division			
7.	12-05/2014-DC (ND-12011(13)/1/2025-eoffice) Enzalutamide 40 mg soft Capsule	M/s Astellas Pharma India Pvt Ltd	The firm has presented the Phase IV clinical trial study report of drug Enzalutamide 40 mg soft Capsules, before the committee. After detailed deliberation, the committee opined that firm needs to submit the more details on Serious Adverse Events including cardiac arrest and multiple organs failure and the data with respect to Cardiovascular events and multiple organs failures observed in PSURs, for further review by the committee.
SND Division			
8.	SND-16011(11)/25/2025-eoffice (Receipt no.58434) Acalabrutinib Capsules 100 mg	M/s Astrazeneca Pharma Limited	Firm did not turn up for the presentation.