

Recommendations of the SEC (Oncology) made in its 13th/25 meeting held on 22.04.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/07/23 Online Submission (38105) HT-6184 2 mg capsule	M/s CBCC Global Research LLP	The firm presented protocol amendment 5.0 dated 26 February 2025 protocol no. HT-6184-MDS-001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/169/23 Online Submission (38138) PF-07220060	M/s Pfizer Limited	The firm presented protocol amendment 2 dated 03 February 2025 protocol no. C4391022. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/137/22 Online Submission (38242) Imlunestrant (LY3484356)	M/s Eli Lilly And Company	The firm presented protocol amendment (e) dated 31 January 2025, protocol no. J2J-MC-JZLH and Increase the number of subjects from 150 to 200 in India. After detailed deliberation, the committee recommended for approval of protocol amendment and Increase the number of subjects from 150 to 200 in India as presented by the firm.
4.	CT/35/23 Online Submission (38258) Mezigdomide, CC- 92480 (BMS-986348)	Bristol-Myers Squibb India Pvt. Ltd	The firm presented protocol amendment 03 dated 21 July 2024 protocol no. CA057008. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
5.	BIO/CT18/FF/2025/47 854 Durvalumab Solution for Infusion 120 mg/2.4ml & 500 mg/10ml	M/s AstraZeneca Pharma India Limited	The firm presented the proposal for approval of additional indication for Durvalumab Solution for Infusion 120 mg/2.4ml and 500mg/10ml [IMFINZI] i.e. Durvalumab in combination with platinum-based chemotherapy, followed by maintenance with Durvalumab in combination with olaparib, is indicated for the first line treatment of patients with advanced or recurrent endometrial cancer based on the results of global clinical studies conducted by the firm.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			<p>The committee noted that the proposed indication is approved by EMA for the maintenance treatment with Durvalumab in combination with olaparib in endometrial cancer that is mismatch repair proficient (pMMR).</p> <p>Also, Olaparib in combination with Durvalumab indicated for the maintenance treatment of adult patients with advanced or recurrent endometrial cancer whose disease has not progressed on first-line treatment with Durvalumab in combination with platinum-based chemotherapy is approved by CDSCO.</p> <p>After detailed deliberation, the committee recommended for the approval of additional indication in line with EMA approved indication i.e. Durvalumab in combination with platinum-based chemotherapy is indicated for the first line treatment of adults with primary advanced or recurrent endometrial cancer who are candidates for systemic therapy followed by maintenance treatment with Durvalumab in combination with olaparib in endometrial cancer that is mismatch repair proficient (pMMR) with the condition that firm should conduct Phase IV study in India for the approved indication. Accordingly, the firm should submit Phase IV study protocol to CDSCO within three months of approval of additional indication.</p> <p>Further, the firm should submit revised indication to CDSCO for further evaluation.</p>
6.	E-75354 Polatuzumab Vedotin for Injection, 140 mg/vial	M/s Roche Products (India) Pvt. Ltd.	<p>The firm presented the proposal to conduct PMS study titled “Post-Marketing Surveillance (PMS) study to monitor the safety of Polatuzumab Vedotin (Polivy®) in india when administered as per local prescribing information in patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma (DLBCL)” vide Protocol No. ML45882</p> <p>After detailed deliberation, the committee recommended for approval to conduct the PMS study as per protocol presented by</p>

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			the firm.
7.	BIO/CT18/FF/2024/46780 Durvalumab Solution for Infusion 120 mg/2.4ml & 500 mg/10ml	M/s. AstraZeneca Pharma India Limited	The firm did not turn up for the presentation.
8.	BIO/CT04/FF/2024/47004 Brentuximab vedotin	M/s. Zydus Lifesciences Limited	<p>The firm presented the proposal for the conduct of Phase III study titled “A prospective, randomized, multicenter, comparative, double-blind, parallel group study to evaluate the efficacy, safety, pharmacokinetics, and immunogenicity of test brentuximab vedotin (ZRC-3318) with reference brentuximab vedotin (Adcetris®), in combination with chemotherapy, in patients with previously untreated stage III or IV classical Hodgkin lymphoma” vide Protocol no. BREN.24.001 Version No. 01 dated 08.11.2024.</p> <p>After detailed deliberation, the committee recommended for approval to conduct Phase III study as per protocol presented by the firm.</p>
BA/BE Division			
9.	BABE/CT05/FF/2024/45753 Mercaptopurine tablets 50 mg	M/s Watson Pharma Pvt. Ltd.	<p>In light of the earlier SEC recommendation dated 21.01.25, the firm presented the amended Protocol No. BE-2388-24, Version 2.0 dated 13/FEB/25.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BABE study with amended protocol, for export purpose only</p>
New Drug Division			
10.	ND/MA/24/000032 Tucatinib Tablets 50mg & 150mg	M/s MSN Laboratories Private Limited	In light of earlier SEC recommendations dated 09.01.2025, the firm presented proposal for grant of permission to manufacture and market of Tucatinib Tablets 50mg and 150mg, along with BE Study report including side effects profile, time versus concentration data of all subjects who participated in the study, inter-subject variability data

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			<p>and literature on Phase-III clinical trial reports of Tucatinib Tablets for Metastatic Breast Cancer, before the committee.</p> <p>After detailed deliberation, the committee noted that the Tucatinib Tablets 50mg/150mg are approved by CDSCO on dated 08.04.2025 and recommended for the grant of permission to manufacture and market of drug product Tucatinib Tablets 50 mg/150mg, subject to the following conditions:</p> <ol style="list-style-type: none"> 1. The drug should be sold by retail under prescription of Oncologist only. 2. The firm should conduct structured Phase IV clinical trial in atleast 200 patients for which the protocol should be submitted within 3 months of approval of the drug for review by the committee. 3. Firm should include the more safety information of Tucatinib Tablets in the Package insert, for which the revised package insert should be submitted to CDSCO. <p>The committee also recommended that firm need to submit six monthly status report of clinical trial including adverse drug events of the drug Tucatinib Tablets, to the CDSCO for further review by the committee.</p>