

Recommendations of the SEC (Oncology) made in its 33th/25 meeting held on 16.10.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/134/25 Online Submission (51937) Ponsegromab (PF-06946860) 154 mg/mL Solution for Injection	M/s. Pfizer Limited	The firm presented phase IIb/III clinical study protocol no.: C3651021 version no. final Protocol amendment 01 dated 25-JUL-2025. 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.
2.	CT/141/25 Online Submission (52162) Sacituzumab Tirumotecan	M/s. MSD Pharmaceuticals Private Limited	The firm presented phase III clinical study protocol no.: MK-2870-036 Version No. 00 dated 22-JUL-2025 After detailed deliberation, the committee recommended for grant of permission to conduct the trial with subject to following condition: 1. The firm shall submit safety data for completed Induction phase. 2. Increase the number of subjects in India.
3.	CT/143/25 Online Submission (52260) Trastuzumab Deruxtecan	M/s. IQVIA RDS (India) Private Limited	The firm didn't turn up for presentation.
Biological Division			
4.	BIO/CT04/FF/2025/50 819 Tislelizumab Injections 100 mg (10 ml/Vial)	M/s. Glenmark Pharmaceuticals Ltd	The firm did not turn up for the meeting.
5.	BIO/CT04/FF/2025/50 535 Pembrolizumab Concentrate for Solution for Infusion 100 mg /4 mL Vial (25 mg/mL)	M/s. Intas Pharmaceuticals Limited	The firm presented a proposal to conduct a Phase I/III clinical trial titled, A Randomized, Double-Blind, Active-Controlled, Parallel, Three Arm, Multicentre Study Comparing Pharmacokinetics, Efficacy, Safety and Immunogenicity of INTP58 and

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			<p>Keytruda, both Administered in Combination with Platinum – Pemetrexed Chemotherapy for the First-Line Treatment in Patients with Metastatic Non-Squamous Non-Small Cell Lung Cancer vide Protocol No.: 0265-24, Version No.: 1.0, Dated 20-Jun-2025 meant for USFDA and EMA submission only.</p> <p>After detailed deliberation, the committee recommended the following changes in the protocol-</p> <ol style="list-style-type: none"> 1. Efficacy parameter should be one of the primary endpoint of the study. 2. Non-inferiority margin should be of 10-12 % for the robustness of the study. 3. Sample size should be recalculated accordingly. <p>Accordingly, the firm should submit revised protocol to CDSCO for further evaluation by the committee.</p>
6.	<p>BIO/CT18/FF/2025/50349</p> <p>Daratumumab Solution for Injection for subcutaneous administration 1800mg (120mg/ml) (Darzalex Faspro)</p>	M/s. Johnson & Johnson Pvt. Ltd.	<p>The firm presented the proposal for the alignment of already approved indications of the drug product Daratumumab Solution for Injection for subcutaneous administration 1800mg (120mg/ml) (Darzalex Faspro) in line with EU SmPC as follows-</p> <ul style="list-style-type: none"> • In combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. • As monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last

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			<p>therapy.</p> <ul style="list-style-type: none"> In combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received one prior therapy containing a proteasome inhibitor and lenalidomide and were lenalidomide-refractory, or who have received at least two prior therapies that included lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or after the last therapy. <p>The firm also presented the revision in prescribing information from version dated 20.01.2025 to version dated 13.06.2025, based on updates in indications in line with EUSmPC and CCDS version no.16 dated 16 Nov 2023, Version no. 18 dated 19 Jun 2024, and Version no.19 dated 15 Sep 2024.</p> <p>After detailed deliberation, the committee recommended for approval of alignment of indications in line with EU SmPC along with update in Prescribing Information Version dated 13.06.2025 as proposed by the firm.</p>
7.	<p>BIO/CT04/FF/2025/51551</p> <p>Serplulimab Concentrate for Solution for Infusion 100 mg/10 mL (10 mg/mL) Vial</p>	<p>M/s. Intas Pharmaceuticals Limited</p>	<p>The firm presented the proposal for grant of permission to conduct Phase IV clinical trial titled “A Single-Arm, Prospective, Interventional, Phase-4 Study to Investigate Safety, Immunogenicity and Efficacy of Serplulimab in Combination with Carboplatin Plus Etoposide as First-Line Therapy in Adult Participants with Extensive-Stage Small Cell Lung Cancer” vide Protocol No. 0234-25 Version 1.0 Version Date:24-Jul-2025</p> <p>The committee noted that approval of drug was granted with Phase III local clinical trial waiver. The committee further noted that Extensive-Stage Small</p>

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			<p>Cell Lung Cancer is quite prevalent in India.</p> <p>After detailed deliberation, the committee recommended the firm to increase the sample size to 200 patients to evaluate the safety and immunogenicity in the Indian population.</p>
New Drugs Division			
8.	ND-12011/10/2024- eoffice Venetoclax	M/s. Tata Memorial Hospital	The firm did not turn up for presentation.
SND Division			
9.	SND-16011(11)/107/2025- eoffice Lenvatinib Capsules 4 mg and 10 mg	M/s. Eisai Pharmaceuticals India Private Limited	<p>In light of earlier SEC recommendation dated 17.06.2025, firm presented Serious Adverse Events reported during the Phase IV CT study along with its assessment reports before the committee.</p> <p>After detailed deliberation, the committee recommended to accept the Phase IV CT study report of Lenvatinib Capsules 4mg and 10 mg.</p>