

**Recommendations of the SEC (Oncology) made in its 27<sup>th</sup>/25 meeting held on 28.08.2025 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/85/24 Online Submission (40303)  Golcadomide (BMS-986369/CC - 99282)	M/s Bristol-Myers Squibb India Pvt. Ltd.	The firm presented protocol amendment 02 dated 07 March 2025 protocol no. CA0731020.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/74/17 Online Submission (40352)  Duvralumab (MEDI4736) and Tremelimumab	M/s AstraZeneca Pharma India Limited	The firm presented protocol amendment version 9.0 dated 24 April 2025 protocol no. D419CC00002.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/92/25 Online Submission (50647)  Rilvegostomig (AZD2936) Concentrate for solution for infusion 50 mg/mL (750mg/vial)  Tremelimumab Concentrate for solution for infusion 20 mg/ml (300 mg/15 ml or 300 mg/vial and 25 mg/1.25 ml or 25 mg/vial)	M/s AstraZeneca Pharma India Limited	The firm presented III clinical study Protocol No.: D7029C00001, CSP Version No. 1.0 dated 04 Dec 2024 and Local CSP - Addendum Version 1.0 dated 27 May 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 in the discussion.
4.	CT/93/25 Online Submission (50656)  Sacituzumab tirumotecan	M/s MSD Pharmaceuticals Private Limited	The firm presented III clinical study Protocol No.: MK2870-032 Version No. 00 dated 18-FEB-2025.  After detailed deliberation, the committee opined that the firm shall submit following justification for further review by the committee.  1. Control arm is not the Standard of care, need rationale for that. 2. The proposed sample size of only 60 patients represents less than 3% of the global study population (N=2400). This appears relatively

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			small and may limit the result findings at our population. It is therefore recommended that the sample size be increased to ensure adequate representation and statistical reliability.
<b>Biological Division</b>			
5.	BIO/CT04/FF/2025/49684  Pembrolizumab concentrate for solution for infusion 100 mg/4 mL vial (25 mg/ml)	M/s Intas Pharmaceuticals Ltd.	<p>The firm presented the proposal for grant of permission to conduct a Phase I/III study titled “A Phase-1/3, Randomized, Assessor-Blind, Active Controlled, Parallel, Two Arm, Multicenter Study, to Compare Efficacy, Safety, Pharmacokinetics, and Immunogenicity of INTP58 versus Keytruda, Both Administered With Platinum-Doublet Chemotherapy, in the First-Line Treatment of Patients With Locally Advanced or Metastatic Squamous or Non-squamous Non Small Cell Lung Cancer” vide Protocol No. 0142-25 version No. 1.0 dated 22 April 2025.</p> <p>After detailed deliberation, the committee recommended for following changes in the protocol-</p> <ol style="list-style-type: none"> <li>1. PFS and OS should be adequately powered and included as an endpoint.</li> <li>2. Inferiority margin should be narrowed.</li> <li>3. Dose of Paclitaxel should be reduced</li> <li>4. Study duration should be increased and OS should be assessed at around 52 weeks</li> <li>5. Sub group analysis should be as per PD-L1 expression also.</li> </ol> <p>Accordingly, firm should submit revised protocol to CDSCO for further evaluation by the Committee.</p>
<b>New Drugs Division</b>			
6.	12-05/2014-DC  Enzalutamide 40 mg soft Capsule	M/s Astellas Pharma India Pvt Ltd	In light of earlier SEC recommendation dated 20.03.2025, firm presented Phase IV clinical trial report of Enzalutamide 40 mg soft Capsule along with the SAEs reported, before the committee.

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			<p>Firm presented study objective, study design, study endpoints, Inclusion and Exclusion criteria, safety assessment, demographic &amp; baseline characteristics, study population, efficacy results, safety results TEAEs reported during study, Drug related Serious TEAEs etc.</p> <p>After detailed deliberation, the committee considered the results of the Phase IV clinical study and recommended that firm should update the phase IV study and SAEs outcome in prescribing information and revised prescribing information should be submitted to CDSCO within one month for further review by the committee</p>
7.	ND/IMP/25/000001 Inavolisib film-coated tablets 3 mg and 9 mg (Itovebi)	M/s Roche Products (India) Private Limited	The firm did not turn up for presentation.
8.	ND/CT/25/000068 Zanubrutinib capsules 80 mg	M/s Glenmark Pharmaceuticals	<p>In line with the condition of the permission for the import and marketing of the drug Zanubrutinib capsules 80 mg, the firm presented Phase IV clinical trial protocol for drug Zanubrutinib capsules 80 mg, before the committee.</p> <p>Firm presented study rationale, Benefit – Risk Assessment, study objective, population and design, sample size justification, safety endpoints, safety endpoints, inclusion/exclusion criteria, assessment schedule, statistical analysis plan etc.</p> <p>After detailed deliberation, the committee noted the numbers of study subjects proposed by firm are very less considering that study is to be conducted for five indications.</p> <p>Accordingly, committee recommended that firm should revised the protocol to include following:</p> <ol style="list-style-type: none"> <li>1) To include more number of study subjects and for sample size calculation efficacy end points should be considered</li> <li>2) Duration of study should be increased.</li> </ol>

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			3) Post-trial access shall be given to subject till progression of disease  Accordingly, firm should submit revised protocol to CDSCO for further review by the committee.