

**Recommendations of the SEC (Oncology) made in its 23<sup>rd</sup>/25 meeting held on 17.07.2025 at CDSCO HQ New Delhi:**

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/172/21 Online Submission (39661)  Elranatamab 40 mg/ mL solution for injection; 1.9 mL/vial	M/s. Pfizer Limited	The firm presented protocol amendment 7.0 dated 7 April 2025 protocol no. C1071007.  After detailed deliberation, the committee recommended for approval of amendment as presented by the firm.
2.	CT/75/25 Online Submission (50038)  Datopotamab Deruxtecan (DS- 1062a) Lyophilised powder for concentrate for solution for infusion 100 mg/vial	M/s AstraZeneca Pharma India Limited	The firm presented phase III clinical study Protocol No.: D763QC00001 Version No. 1.0 dated 26-FEB-2025 and Local CSP -Addendum IND-1, version 1.0 dated 21 April 2025.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/119/23 Online Submission (39785)  SB27 (proposed pembrolizumab biosimilar)	M/s Fortrea Development India Private Limited	The firm presented protocol amendment version 4.0 dated 28 April 2025 protocol no. SB27-3004.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm with condition that firm must meet the initial recruitment target for India.
<b>Biological Division</b>			
4.	e-office file no.: rDNA- 11015/1/2025- eoffice r-DNA- 11015/1/2025- eoffice (E-78331 dated 04/03/2025)  Nivolumab (10 mg/ml) concentrate for solution for infusion	M/s Bristol-Myers Squibb India Pvt. Ltd.	The firm presented a proposal to conduct a non-interventional, retrospective, observational study titled: "A multicenter observational study to explore the outcomes of use of nivolumab (or anti-PD1) monotherapy in Indian patients with recurrent or metastatic SCCHN in a real-world setting: a retrospective chart review" (Protocol No.: CA209-1525, Protocol version: Original Protocol dated 11 Nov 2024).  After detailed deliberation, the committee recommended for grant of permission to conduct the retrospective, observational post-marketing surveillance study as per

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			the protocol presented by the firm with the condition that the study shall be conducted using a single-dose.
5.	BIO/CT04/FF/2025/48 266  Pegfilgrastim 6 mg/ 0.6 mL.	M/s Syngene International Limited	<p>The firm presented the proposal to conduct Phase I clinical trial titled “A Randomized, Open-label, Single-dose, Three-period, Two-treatment, Three-sequence, Partial Replicate Crossover Study to Compare the Pharmacokinetics, Pharmacodynamics, Safety and Tolerability of Fulphila OBI kit and Fulphila PFS (pegfilgrastim) for manual use in Normal Healthy Male Volunteers, as per protocol number SYNCD-052-24/BIO-PEGFIL-102 Version-2.0 dated-05-Jun-2025.</p> <p>The committee has noted that proposed drug Pegfilgrastim in prefilled syringes (PFS) is approved in more than 45 countries including USA, EU, Canada, Australia, Switzerland, and the current submission represents a line extension approval in EU/USA.</p> <p>After detailed deliberation, the committee recommended for submission of the following information for further evaluation:</p> <ol style="list-style-type: none"> <li>1. In-use stability data of the drug when with the OBI kit</li> <li>2. Data on the functionality and performance evaluation of the OBI device.</li> </ol> <p>Accordingly, the firm shall submit the above information for further evaluation by the SEC.</p>
<b>BA/BE Division</b>			
6.	BABE/CT05/FF/2025/ 49066  Ibrutinib 560 mg Film-Coated Tablet	M/s Veeda Clinical Research Limited	<p>Firm presented the BA/BE study Protocol No. 25-VIN-0162, Version No. 01, Protocol Date 16-APR-2025 for conducting BA/BE study for export purpose only, before the committee.</p> <p>After detailed deliberation, the committee</p>

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			recommended for grant of permission to conduct the BABE study for export purpose only
<b>New Drugs Division</b>			
7.	ND/MA/25/000064  Lurbinectedin for Injection 4 mg/Vial	M/s Zydus Lifesciences Limited	<p>The firm has presented its proposal for grant of permission to manufacture and market of new drug Lurbinectedin Injection 4mg/vial along with the request for local Clinical Trial waiver and Bioequivalence study waiver before the Committee.</p> <p>After detailed deliberation, the committee recommended for waiver of Bio-equivalence study and opined that firm should conduct Phase III clinical trial in Indian population.</p> <p>Accordingly, the firm should submit Phase III Clinical Trial protocol to CDSCO for further review by the committee.</p>
8.	ND/IMP/25/000038  Vorasicenib Tablets 10 mg & 40 mg	M/s SERVIER INDIA PRIVATE LIMITED	<p>The firm presented its proposal for grant of permission to import and market of Vorasicenib Tablets 10 mg &amp; 40 mg along with the request for local Phase-III Clinical Trial waiver, before the committee.</p> <p>The committee noted that drug Vorasicenib Tablets 10 mg &amp; 40 mg met orphan drug status in other countries. The prescribing information of applied product was also reviewed by the committee and found in-line with the recommendations in other countries.</p> <p>The firm assured the committee to conduct Phase-IV clinical trial on Indian patients and to provide post-trial access to these trial patients.</p> <p>After detailed deliberation, the committee opined that there is an unmet medical need for the treatment of proposed indications in the country.</p>

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			<p>Accordingly, the committee recommended for the grant of permission to manufacture and market of the drug Vorasidenib Tablets 10 mg &amp; 40 mg with local Phase III clinical trial waiver.</p> <p>Further committee recommended that the firm should conduct Phase IV clinical trial for which the protocol should be submitted to CDSCO within 3 months of approval of the drug for review by the committee.</p>