

**Recommendations of the SEC (Oncology) made in its 04<sup>th</sup>/25 meeting held on 29.01.25 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/73/23 Online Submission (36610) Pembrolizumab 200 mg + Vibostolimab 200 mg	MSD Pharmaceuticals Pvt. Ltd.	The firm presented protocol amendment 05 dated 11 October 2024 protocol no. 003-05.  After detailed deliberation, the committee opined that the firm should submit for following for further review by the committee. 1. Interim analysis data/external data has on which amendment proposed for change of primary and secondary objective/ end point. 2. Other country regulatory approval for proposed amendment.
2.	CT/38/24 Online Submission (36611) SKB264 (MK-2870)	MSD Pharmaceuticals Pvt. Ltd.	The firm presented protocol amendment 03 dated 15 November 2024 protocol no. MK-2870-010. After detailed deliberation, the committee opined that the firm should submit more justification for change in inclusion criteria for further review by the committee.
3.	CT//53/24 Online Submission (42731) FYB206 (Pembrolizumab)	Synoes Health India Pvt. Ltd.	The firm didn't turn up for presentation.
4.	CT/123/22 Online Submission (36769) Datopotamab Deruxtecan (Dato-DXd, DS-1062a) (100mg/vial) Durvalumab (MEDI4736) 50mg/ml: 500mg/vial	M/s Astrazeneca Pharma India Limited	The firm presented protocol amendment version 3.0 dated 04 November 2024 protocol no. D926NC00001.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
<b>Biological Division</b>			
5.	BIO/CT04/FF/2024/4 6058  Trastuzumab Solution	M/s. Intas Pharmaceuticals Ltd.	The firm presented the proposal to conduct Phase I clinical trial titled "A randomized, double-blind, single-dose, Phase I, parallel group study to

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	for Injection 600 mg/5 mL vial (sc)		compare the pharmacokinetics, safety, tolerability, and immunogenicity of trastuzumab from three subcutaneous (SC) injection formulations: the test product (Zercepac 600 mg) and the reference products (EU-sourced Herceptin® 600 mg and US-sourced Herceptin® Hylecta 600mg) in healthy adult male subjects” vide Protocol Number: 0204-24,Version: 1.0 dated 02-Oct-2024. After detailed deliberation the committee recommended for approval to conduct the clinical trial as per the protocol presented by the firm.
6.	BIO/CT18/FF/2024/45484  Serplulimab Concentrate for Solution for Infusion 100 mg/10 ml Vial	M/s. Intas Pharmaceuticals Ltd.	The firm presented the proposal to import and market Serplulimab concentrate for solution for Infusion 100 mg/10 ml vial for the indication Serplulimab in combination with carboplatin and etoposide is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) with waiver of local clinical trial. The firm claimed that US has provided orphan designation for the drug and EU has provided positive opinion. The committee noted that the drug is approved in China, Indonesia, Columbia etc. and not approved in any of the countries mentioned under Rule 101 of NDCT Rules 2019 and no safety data is available in Indian population. After detailed deliberation, the committee did not recommend the proposal of the firm to import and market import and market Serplulimab concentrate for solution for Infusion 100 mg/10 ml vial with Phase III clinical trial waiver.
7.	BIO/CT04/FF/2024/46007  Trastuzumab 150 mg powder for concentrate for solution for infusion	M/s. CuraTeQ Biologics Private Limited	The firm presented the proposal to conduct Phase IV clinical trial titled “A Phase IV Post-Marketing Study Evaluating the Safety, and Effectiveness of BP02 (Trastuzumab) as per Approved Prescribing Information” vide Protocol number: BP02-401, Version 1.0 Dated 11/10/2024.

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			<p>After detailed deliberation, the committee recommended the firm to conduct the clinical trial with the following conditions:</p> <ol style="list-style-type: none"> <li>1) Free of cost concomitant medication shall be provided to the study subjects during the trial.</li> <li>2) Free of cost drug to be provided to the study subjects those who are responding as per the PI discretion after the trial duration.</li> <li>3) All Study Investigators should be medical oncologist</li> <li>4) The terminology of breast cancer should be clearly defined in the inclusion and exclusion criteria.</li> </ol> <p>Accordingly, the firm should submit revised protocol to CDSCO for further evaluation.</p>
<b>SND Division</b>			
8.	SND/CT/20/000045 Pegaspargase Injection 3750 IU/5ml	M/s.Gennova Biopharmaceutical s Ltd	<p>In light of the earlier SEC (Oncology &amp; Hematology) dated 08.09.2021 &amp; 09.09.2021, firm has presented the revised Phase-IV clinical trial protocol no. GBL/PEGASP/ALL/2020/01 version no.1.3 dated 06.05.2024 before the committee.</p> <p>After detailed deliberation, the committee recommended for the conduct of the Phase-IV clinical trial study as per the protocol presented by the firm with the condition that study shall be conducted in atleast 5 geographically distributed clinical study sites. After completion of the clinical trial, firm shall submit the clinical study report to the CDSCO for further review by the committee</p>
9.	e-receipt no. 50681/2024/CRU (Computer No.50681)  Ruxolitinib Tablets 5mg, 10mg,15mg & 20mg	M/s. Novartis Healthcare Private Limited	The firm did not turn up for the presentation.
10.	SND/IMP/24/000088  Acalabrutinib Pharma	M/s. Astrazeneca Pharma Limited	The firm did not turn up for the presentation.

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