

**Recommendations of the SEC (Oncology) made in its 23<sup>rd</sup>/24 meeting held on 12.11.2024 at CDSCO (HQ), New Delhi:**

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	GCT/PostAppr/2024/35204 Online Submission (35204)  Nivolumab	M/s. Dr. Reddy's Laboratories Limited	The firm presented waiver of condition that investigator shall be Medical Oncologist at each site." protocol No.: NU-01-001.  After detailed deliberation, the committee recommended to modify the condition mentioned in post approval NOC as "Subjects shall be enrolled only in sites having Medical Oncologist as Principal Investigator (PI) w.e.f. 24.09.2024".
2.	GCT/CT04/FF/2024/45756 Online Submission (45756)  OX-4224 (Evixapodlin)	M/s. Klinera Global Services	The firm didn't turn up for presentation.
<b>Biological Division</b>			
3.	BIO/CT04/FF/2024/45130  Pegfilgrastim PFS 0.6mL solution for injection (single dose study)	M/s. CuraTeQ Biologics Private Limited	The firm presented the clinical study proposal to conduct Phase I clinical trial titled "Single dose study to compare pharmacokinetic, pharmacodynamics, immunogenicity and safety of BP14 (Pegfilgrastim) 6mg/06mL solution in single use pre-filled syringe and US-licensed Neulasta (Pegfilgrastim) 6mg/0.6mL solution for injection in healthy adult male subjects" vide protocol number C1B04734 (sponsor protocol No. BP14-104) version No. 01 dated 17.08.2024.  After detailed deliberation, the committee recommended for grant of permission to conduct the phase 1 clinical trial for export purpose as per protocol presented by the firm.
4.	BIO/CT04/FF/2024/45136  Pegfilgrastim 6mg/0.6mL solution in single PFS (multi dose study)	M/s. CuraTeQ Biologics Private Limited	The firm presented the clinical study proposal to conduct Phase I clinical trial titled "Multiple dose study to compare immunogenicity and safety of BP14 (Pegfilgrastim) 6mg/06mL solution in single use pre-filled syringe and US-licensed Neulasta (Pegfilgrastim) 6mg/0.6mL solution for injection in

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			<p>healthy adult male subjects” vide protocol number C1B04735 (sponsor protocol No. BP14-105) version No. 01 dated 17.08.2024.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the phase 1 clinical trial for export purpose as per protocol presented by the firm.</p>
5.	<p>E receipt no 56136</p> <p>Recombinant L-asparaginase-II for injection 10000 IU vial</p>	M/s. Genova	<p>The firm presented the safety data of first 20 subjects/first two cohorts of the approved Phase-I clinical trial study as per the condition mentioned in Form CT-06 vide file No. BIO/CT/23/000120 dated 18.04.2024 that “The firm should submit safety data of first 20 subjects/first two cohorts enrolled in the study for evaluation by the committee and further continuation of the study”.</p> <p>The committee noted the results of the safety data presented by firm and recommended for further continuation of the study.</p>
6.	<p>BIO/CT18/FF/2024/45080</p> <p>Trastuzumab Deruxtecan 100 mg Powder for Concentrate for Solution for Infusion</p>	M/s. AstraZeneca Pharma India Limited	<p>The firm presented the proposal for the approval of additional indication of the drug Trastuzumab Deruxtecan 100 mg powder for concentrate for solution for infusion i.e., for the treatment of adult patients with unresectable or metastatic HER2-positive (IHC3+) solid tumors who have received prior treatment or who have no satisfactory alternative treatment options under unmet need in the country.</p> <p>The committee noted that firm has obtained accelerated approval in US for the proposed additional indication based on Phase II study. Further, it was noted that there is no clinical data available in Indian subjects for the applied additional indication.</p> <p>After detailed deliberation, the committee recommended to submit the clinical data in Indian subjects for the applied additional indication.</p>
<b>BA/BE Division</b>			
7.	BABE/CT05/FF/2024/44755	M/s. Cliantha Research Limited	The firm presented the protocol No.: C1B03305, Ver. 01, dated 25.07.2024 for

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	Palbociclib/Letrozole 125 mg/2.5 mg film-coated tablets		BA/BE study for export purpose.  After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BA/BE study with the condition that Medical Oncologist should be a part of BA/BE Study team.
8.	BABE/CT05/FF/2024 /44620  Nilotinib 68 mg Tablets	M/s. Ecron Acunova Limited	The firm presented the protocol No.: 105-24, Ver. 1 dated 01.07.2024 for BA/BE study for export purpose.  After detailed deliberation, the committee recommended for grant of permission to conduct the BE study for export purpose only.