Recommendations of the SEC (Oncology) made in its 17th/25 meeting held on 21.05.2025 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/38/24 Online Submission (36611) SKB264 (MK-2870)	M/s MSD Pharmaceuticals Private Limited	In light of earlier SEC Recommendation dated 29.01.2025, the firm presented protocol amendment 03 dated 15 November 2024 protocol no. MK-2870-010. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/50/24 Online Submission (42642) LEE011 (Ribociclib)	M/s Novartis Healthcare Private Limited	The firm presented phase IIIb clinical study protocol no.: CLEE011O12001 Version no. 02 dated 08-Jan-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.
3.	CT/34/25 Online Submission (48701) AAA817 - [225Ac]Ac-PSMA-617	M/s Novartis Healthcare Private Limited	The firm presented phase III clinical study protocol no.: CAAA817B12301 version no. 00 dated 17-JAN-2025. After detailed deliberation, the committee opined that the proposal will be deliberated in presence of Nuclear medicine expert.
4.	CT/35/25 Online Submission (48726) Belantamabmafodotin	M/s Pharmaceutical Research Associates India Private Limited	The firm presented phase III clinical study protocol no.: 214828 amendment 1 version no. 2.0 dated 12-NOV-2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
5.	CT/100/19 Online Submission (38745) LY3527723 (LOXO-292)	M/s. Eli Lilly and Company (India) Pvt. Ltd.	The firm presented Protocol Amendment (J) 12-Nov-2024 protocol no. J2G-MC-JZJB. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
6.	CT/73/23 Online Submission (36610) Pembrolizumab 200mg + Vibostolimab 200mg	M/s MSD Pharmaceuticals Private Limited	The firm didn't turn up for presentation.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
7.	BIO/CT18/FF/2024/46258 Talquetamab solution for injection 2 mg/mL and 40 mg/mL	M/s Johnson & Johnson Pvt. Ltd.	The firm presented the proposal to import and market the new drug product Talquetamab solution for injection 2mg/mL and 40mg/mL for the indication i.e "Talquetamab, as monotherapy is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma, who have previously received at least 3 prior therapies, including a proteosome inhibitor, an immunomodulatory agent and an anti-CD38 antibody" based on the clinical data generated from the Phase I/II global clinical study along with request of waiver of local clinical trial. The committee noted that the Phase III global clinical trial in which India is a participant is ongoing and at present there is no safety and efficacy data in Indian population. Further, the committee noted that there is no unmet need in the country for the proposed indication. After detailed deliberation, the committee recommended the firm to submit safety and efficacy results in Indian subset of patients after completion of Phase III global clinical trial to CDSCO for further evaluation before the committee.
8.	BIO/CT04/FF/2025/47762 Daratumumab Concentrate for Solution for Infusion 100 mg/5 mL Vial and 400 mg/20 mL Vial	M/s INTAS PHARMACEUTICALS LTD	The firm presented the protocol to conduct Phase I/III study titled "A prospective, Randomized, Double Blind, Active Controlled, Multi Center, Two Arm, Phase I/III study to investigate Safety, Efficacy, Pharmacokinetics and Immunogenicity of Intas Daratumumab (INTP33) compared of DARZALEX® in Transplant-Ineligible participants with newly diagnosed Multiple Myeloma" vide Protocol No. 0327-24 Version 1.0 dated 01 Jan 2025. After detailed deliberation, the committee recommended for grant of permission to conduct Phase I/III study as per the protocol presented by the firm with the condition to provide post trial access treatment to trial subjects who will be benefitted from the study drug as per

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			NDCT Rules.
9.	BIO/CT04/FF/2025/48114 Pertuzumab Concentrate for Solution for Infusion 420 mg/14 mL Vial (30 mg/mL)	M/s INTAS PHARMACEUTICALS LTD	The firm presented the protocol to conduct Phase III study titled "A prospective, Randomized, Double Blind, Parallel-Arm, comparative, Phase III study to evaluate the efficacy, safety, Pharmacokinetics and Immunogenicity of Pertuzumab Biosimilar of Intas Pharmaceuticals Limited Against Perjeta® in Adult patients with HER2-Positive Hormone Receptor Negative Locally Advanced or Early Breast Cancer" for export purpose vide Protocol No. 0508-23 Version 1.0 dated 18 Oct 2024. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III study as per the protocol presented by the firm.
10.	BIO/CT18/FF/2024/46779 Daratumumab Solution for Injection 1800 mg	M/s. Johnson and Johnson Private Limited	The firm did not turn up for the presentation.