Recommendations of the SEC (Oncology) made in its 16th/25 meeting held on 13.05.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/22/25 Online Submission (48050) PF-08046047 - SGNB6A – SigvotatugVedotin	M/s Pfizer Limited	The firm presented phase III clinical study protocol no. C5751003. Amendment 01 dated 06-FEB- 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by firm.
2.	CT/109/23 Online Submission (37793) Talquetamab	M/s Johnson & Johnson Pvt. Ltd.,	The firm presented protocol amendment 3 dated 19 December 2024 and Protocol Amendment 4 dated 23 Jan 2025 protocol no. 64407564MMY3009. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/83/22 Online Submission (37823) BCD-201	M/s IR Innovate Research Private Limited	The firm didn't turn up for presentation.
4.	CT/122/24 Online Submission (37845) GIM-122	CBCC Global Research LLP	The firm presented protocol amendment version 4/India 2, dated 07 February 2025 Protocol no. GIM122-CT01. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
5.	CT/40/24 Online Submission (37868) Pembrolizumab (BAT3306)	M/s IQVIA RDS (India) Private Limited,	The firm presented protocol amendment 1 version 2.0 dated 04 November 2024 protocol no. BAT-3306-002-CR. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
6.	CT/11/23 Online Submission (37865) TAR 200, Cetrelimab	M/s Johnson & Johnson Pvt. Ltd	The firm presented protocol amendment 3 dated 11 October 2024 protocol no. 17000139BLC3002. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
7.	BIO/CT04/FF/2024/47010 Pegfilgrastim 6 mg/0.6mL PFS	M/s. Intas Pharmaceuticals Ltd.	The firm presented the proposal to conduct Phase I study titled "A Randomized, balanced, open-label, two-treatment, two-period, two sequence, single dose, crossover, comparative bioavailability study of INTP5 Pegfilgrastim of Intas Pharmaceuticals Limited, India when delivered automatically from the On Body Injector (OBI) delivery device (test product) versus INTP5 (ENNUMO^{TM}) PFS, when delivered manually from a pre-filled syringe (reference product) in normal, healthy, adult, human subjects" vide Protocol No.: 0156-22; Version No. 1.0; Dated: 11.10.2024. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I clinical study as per the protocol presented by the firm.
8.	BIO/CT18/FF/2024/45484 Serplulimab Concentrate for Solution for Infusion 100 mg/10 ml Vial	M/s. Intas Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 29.01.2025, the firm presented the additional data for seeking approval to import and market Serplulimab Concentrate for Solution for Infusion 100 mg/10 ml Vial based on the safety and efficacy data generated from global clinical studies along with a request of local clinical trial waiver. The committee noted that drug is now approved in EMA and the drug falls under the category of Orphan Drug. After detailed deliberation, the committee recommended for the grant of permission to import and market the drug with the condition to conduct Phase-IV clinical trial in India. Accordingly, firm shall submit Phase IV Clinical Trial protocol to CDSCO within 03 months of grant of marketing authorization.
9.	BIO/CT04/FF/2025/48518 Nivolumab 150 mg/10mL vial	M/s. Alkem Laboratories Ltd.	The firm did not turn up for presentation.