Recommendations of the SEC (Oncology) made in its 05th/24 meeting held on 05.03.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/169/23 Online submission (41222) PF-07220060 100 mg Tablets	M/s. Pfizer	The firm presented Phase III clinical trial study protocol No. C4391022 final protocol dated 30 Jun 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by firm with condition that justification for sample size in India compared to global sample size shall be submitted to CDSCO.
2.	CT/21/24 Online submission (41796) PF-06463922 (Lorlatinib) 25 mg	M/s. Pfizer	The firm presented Phase IV clinical trial study protocol No. B7461039 amendment 1 dated 19.07.2022. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by firm.
3.	CT/25/23 Online submission (31011) Camizestrant (AZD9833)	M/s. Fortea Development	The firm presented protocol No. D8531C00002, for waiver of condition No. (i) & (ii) mentioned in CT NOC. After detailed deliberation, the committee opined that response submitted by the firm for waiver of CT NOC condition (i) and (ii) is not accepted and more justification is required to be submitted for further review by the committee.
4.	CT/103/21 Online Submission (31083) Trastuzumab Deruxtecanas	M/s. AstraZeneca	The firm presented protocol amendment version 3.0 dated 14 December 2023 and increase the number of subjects from India protocol No. D967SC00001. After detailed deliberation, the committee recommended for approval of protocol amendment and increase the number of subjects in India (from 25 to 28) as presented by the firm.
5.	CT/68/20 Online Submission (31221) Amivantamab and Lazertinib	M/s. J&J	The firm presented protocol amendment 4 dated 14 November 2023 protocol No. 73841937NSC3003. After detailed deliberation, the committee recommended for approval of protocol

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			amendment as presented by the firm.
6.	CT/13/20 Online Submission (31196) Osimertinib	M/s. AstraZeneca	The firm presented protocol amendment. version 3.0 dated 20 November 2023 protocol No. D5169C00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
7.	CT/111/22 Online Submission (31232) Teclistamab	M/s. J&J	The firm presented protocol amendment 3.0 dated 27 September 2023 protocol No. 64007957MMY3006 After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
8.	CT/25/24 Online Submission (42032) ALT-803 (N-803)	M/s. CBCC Global Research	The firm presented Phase IIb clinical study protocol No. CA-ALT-803-01-14, QUILT-2.005 version 14 dated 15/Feb/2024 After detailed deliberation, the committee opined that more stratified data of adverse events including SAE along with causality assessment shall be submitted for further review by the committee.
9.	CT/176/22 Online submission (31345) Atezolizumab, Lenvatinib & Sorafenib	M/s. Roche	The firm presented protocol amendment version 4 dated 09 November 2022 and protocol amendment version 5 dated 31 March 2023 protocol no. MO42541 After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
10.	CT/27/24 Online Submission (42090) ISB 1442	M/s. Glenmark	The firm presented Phase I/II clinical study protocol No. ISB 1442-102, version 1.0 dated 16 Feb 2024. After detailed deliberation, the committee opined that the firm shall submit current safety data including data of Indian subjects from already approved clinical trial in India for further review by the committee.
11.	CT/110/22 Online Submission (31415) Xevinapant	M/s. IQVIA	The firm presented protocol amendment version 6.0 dated 18 October 2023 protocol No. MS202359_0002 After detailed deliberation, the committee

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			recommended for approval of protocol amendment as presented by the firm.