Recommendations of the SEC (Oncology) made in its 02nd/24 SEC meeting held on 23.01.2024& 24.01.2024 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/153/23 Online Submission (40374) Repotrectinib (BMS-986472, TPX-0005)	M/s. BMS	The firm presented phase III Clinical study protocol no. CA127-1030. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following conditions: 1) More government sites shall be included in the study. 2) Sample size should be at least 50 patients from India.
2.	CT/11/23 Online Submission (29854) TAR 200 Cetrelimab BCG	M/s. Johnson & Johnson	The firm presented protocol amendment 2 dated 17 May 2023, protocol no. 17000139BLC3002. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
3.	CT/158/23 Online Submission (40809) Rusfertide (PTG-300)	M/s. JSS Medical Research Asia Pacific Private Limited	The firm presented phase III Clinical study protocol no. PTG-300-21. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
4.	CT/124/22 Online Submission (29888) ABL001 (Asciminib)	M/s. Novartis Healthcare Private Limited	The firm presented protocol amendment version 01 dated 13 September 2023, protocol no. CABL001J12302. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
5.	CT/33/23 Online Submission (30035) Pacritinib (SB1518)	M/s. PSI CRO Pharma Pvt. Ltd.	The firm presented protocol amendment 10 version 3.0 dated 21/09/2023 protocol no. PAC303. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.

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6.	CT/19/23 Online Submission (30064) Gedatolisib Lyophilized Powder for Infusion	M/s. PSI CRO Pharma Pvt. Ltd.	The firm presented protocol amendment version 5.0 dated 20/09/2023 protocol no. CELC-G-301. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
7.	CT/48/20 Online Submission (30092) Capivasertib + Abiraterone	M/s. AstraZeneca Pharma India Limited	The firm presented protocol amendment version 3.0 dated 01/Sep/2023 protocol no. D361BC00001. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
8.	CT/167/23 Online Submission (41078) Osimertinib	M/s. Fortrea Development India Private Limited	The firm presented phase II Clinical study protocol no. D516AC00003. After detailed deliberation, the committee recommended that the firm should submit rationale for duration of treatment post CCRTfor further review by the committee.
9.	CT/100/22 Online Submission (30242) JDQ443	M/s. Novartis Healthcare Private Limited	The firm presented protocol amendment version 01 dated 06/June/2023 protocol no. CJDQ443B12201. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
10.	CT/35/23 Online Submission (29983) Mezigdomide, CC-92480 (BMS-986348)	M/s. Bristol-Myers Squibb India Pvt. Ltd.	The firm presented protocol amendment version 2 dated 06 July 2023, protocol no. CA057008. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
11.	CT/100/20 Online Submission (29942) TrastuzumabDeruxtecan	M/s. AstraZeneca	The firm presented protocol amendment version 4.0 dated 19/September/2023 and local addendum IND-1 version 2.0 dated 03 November 2023 protocol no. D967JC00001. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by

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			the firm.
12.	CT/90/18 Online Submission (30440) Durvalumab plus Bevacizumab	M/s. AstraZeneca	The firm presented protocol amendment version 5.0 dated 29/November/2023 protocol no. D933GC00001. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
13.	CT/149/23 Online Submission (40571) AP063	M/s. InVentiv	The firm presented phase III Clinical study protocol no. AP063-003. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
14.	CT/95/23 Online Submission (38850) Pertuzumab (r-DNA origin) injection 420 mg/14 mL vial (Bmab 1500) or PERT-IJS	M/s. Biocon Biologics Limited	In light of earlier SEC recommendation dated 30.10.2023 & 31.10.2023, the firm presented clarification for statistical part of protocol, details of pathological evaluations and other details before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the phase 3 clinical trial protocol no. BIO-PERTUZ-301 as presented by the firm. **(**Dr. Kaushal Kalra did not participate in this proposal.)
15.	CT/123/22 Online Submission (30441) DatopotamabDeruxtecan (Dato-DXd, DS-1062a) (100mg/vial) Durvalumab (MEDI4736)50mg/ml: 500mg/vial	M/s. AstraZeneca	The firm presented protocol amendment version 2.0 dated 25/October/2023 protocol no. D926NC00001. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
16.	CT/151/23 Online Submission (40605) AZD5305 20mg/Placebo	M/s. AstraZeneca	The firm presented phase III Clinical study protocol no. D9723C00001. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.

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17.	CT/81/18 Online Submission (28922) Durvalumab	M/s. AstraZeneca	In light of earlier SEC recommendation dated 21.12.2023 & 22.12.2023, the firm presented detailed justification before the committee. After detailed deliberation, the committee recommended for approval of the protocol amendment version 6.0 dated 28 August 2023 as presented by the firm.
18.	CT/140/23 Online Submission (40457) Nivolumab (DRL_NU)	M/s. Dr. Reddy's Laboratories	In light of earlier SEC recommendation dated 21.12.2023 & 22.12.2023, the firm presented Phase I/III protocol no. NU-01-001 along with other detailsbefore the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Biological Division			
19.	BIO/CT18/FF/2023/40177 Pembrolizumab Injection 100mg/4ml	M/s.MSD Pharmaceutical Private Limited	The firm did not turn up for the presentation.
20.	BIO/CT21/BO/2023/40418 Pertuzumab 30 mg/ml	M/s Zydus Lifesciences Limited	The firm presented their proposal for grant of permission to manufacture and market Pertuzumab 30mg/mL concentrate solution for infusion (420 mg / 14 mL single-dose vial) based on the results of comparative Phase III clinical trial conducted in India to establish the efficacy, safety, pharmacokinetics and immunogenicity of the drug product. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Pertuzumab 30mg/mL concentrate solution for infusion (420 mg / 14 mL single-dose vial) for the indication of metastatic breast cancer subject to the condition that the firm shall conduct Phase IV study in the country. Accordingly, the protocol to conduct the Phase IV study shall be submitted within three months of grant of marketing authorization permission to manufacture

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			and market the product.
New Drug Division			
21.	ND/MA/23/000124 Ferric Maltol Capsules 30mg	M/s. Synokem Pharmaceuticals Pvt. Ltd.	The firm has presented their proposal for grant of permission for manufacturing and marketing of the drug along with protocol for the Bioequivalence study and waiver of phase III Clinical trial before the committee. After detailed deliberation, the committee recommended for the grant of permission to conduct the Bioequivalence study as per the protocol presented. The firm should submit the Bioequivalence study results before the committee for further consideration.
22.	ND/MA/23/000111 Relugolix Tablets 120 mg	M/s. BDR Pharmaceutical	In light with earlier SEC recommendation dated 12.09.2023, the firm has presented bioequivalence study results before the committee along with justification regarding variability in concentration of drug in BE study data and clarification regarding the concentration of the drug in CSF. The committee noted that the drug is already approved in country on 16.10.2023. After detailed deliberation, the committee recommended for grant of permission to manufacture and market of drug Relugolix Tablets 120mg with condition that the firm should conduct Phase IV clinical trial for which the protocol should be submitted within 3 months of approval of the drug for review by the committee.