Recommendations of the SEC (Oncology) made in 03rd/24 SEC meeting held on 07.02.2024 & 08.02.2024 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/23/000111 Online Submission (39541) Daratumumab	M/s. Spectrum Clinical Research Private Limited	In light of earlier SEC recommendation dated 29.11.23 and 30.11.23, the firm presented Phase III clinical study protocol No. BCD-264-2/DARVIVA. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/137/23 Online Submission (40392) 1.Datopotamab deruxtecan(Dato-DXd, DS-1062a) 100mg/vial 2.Durvalumab (MEDI4736) 500mg/vial (50mg/mL)	M/s. AstraZeneca	In light of earlier SEC recommendation dated 21.12.23 and 22.12.23, the firm presented Phase III clinical study protocol No. D7630C00001 version 2.0 dated 11 September 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/102/23 Online Submission (39131) Belantamab Mafodotin (GSK2857916) for Injection 100mg	M/s. GSK Pharma	In light of earlier SEC recommendation SEC dated 07.12.23 and 08.12.23, the firm presented results of adverse events on the ongoing study and toxicity profile of Indian subjects, protocol No. 209664. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I clinical trial with the condition that quarterly data of adverse events shall be submitted to CDSCO.
4.	CT/21/000087 Online Submission (30961) Giredestrant 30mg hard capsules Anastrozole 1mg film-coated tablets Exemestane 25mg film-coated tablets Letrozole 2.5mg film-coated tablets Tamoxifen 20mg tablets	M/s. Roche	The firm presented protocol amendment version 5.0 dated 25 August 2023 protocol No. GO42784. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm

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5.	CT/22/000046 Online Submission (30695) Datopotamab Deruxtecan (Dato-Dxd, Ds-1062)	M/s. AstraZeneca	The firm presented to Increase the number of subject from 23 to 30 protocol No. D926PC00001 After detailed deliberation, the committee recommended for approval of Increase the number of subject from 23 to 30 in India as presented by the firm.
6.	CT/21/000044 Online Submission (30696) Atezolizumab Injection 1200mg/20ml	M/s. Roche	The firm presented protocol amendment version 4.0 dated 14 March 2023 protocol No. WO42633 After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm
7.	CT/20/000103 Online Submission (30560) Osimertinib	M/s. AstraZeneca	The firm presented protocol amendment version 4.0 dated 05 July 2023 protocol No. D516AC00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm
8.	CT/24/000007 Online Submission (41477) Leuprolide acetate for injectable suspension, 30 mg	M/s. CBCC Global Research LLP	The firm presented Phase III clinical study protocol No. TOL2506A, version 4.0 dated 23/November/2022. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
9.	Online Submission (41452) GME751(Pembrolizumab) concentrate for solution for infusion25 mg/mL (100 mg/vial)	M/s. Parexel	The firm didn't turn up for presentation.
10.	Online Submission (41640) ISB 2001	M/s. Glenmark Pharmaceuticals	The firm presented Phase 1 clinical study protocol No. ISB 2001-101 version 2.0 amendment 01 dated 07/April/2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.

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11.	CT/150/23 Online Submission (40705) Dostarlimab (GSK4057190A)	M/s GSK	The firm presented Phase III clinical study protocol No. 221530 dated 16 October 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm
Biological Division			
12.	4-25/Roche/PAC-R-Atezolizumab-2022-BD(Diary no 6987) Atezolizumab injection 1200mg/20ml and 840mg/40mg vial	M/s. Roche	The firm presented the proposal for modification of approved indication of the drug Atezolizumab injection (1200mg/20ml and 840/40rng vials) [Tecentriq] in line with indication approved by EMA. After detailed deliberation, the committee recommended the following- 1. The firm should submit statistical data supporting the clinical endpoints from the conducted studies for further evaluation. 2. The firm should clarify the reason for withdrawal of indications in USFDA along with its current status. 3. The firm should clarify the reason for withdrawal of approval from USFDA and continual of approval in EMA for the modified indication. Accordingly, the firm should submit the above clarifications to CDSCO for further evaluation by the committee.
13.	BIO/CT18/FF/2023/40177 Pembrolizumab Injection 100mg/4ml	M/s. MSD Pharmaceutical Private Limited	The firm presented the proposal for approval of additional indications mentioned below for the drug Pembrolizumab injection (Keytruda)100mg/4mL(25mg/mL) solution in a single vial based on the data generated from global clinical trials with a request for local clinical trial waiver: • Pembrolizumab as a monotherapy is indicated for the adjuvant treatment of adults with Stage III melanoma and lymph node involvement who have undergone complete resection. • Pembrolizumab as a monotherapy is indicated for the first-line treatment

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			of metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (MMR) colorectal cancer in adults. • Pembrolizumab as a monotherapy is indicated for the treatment of adult with relapsed or refractory classical Hodgkin lymphoma who have failed autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT is not a treatment option. The committee noted that the drug falls under the orphan drug category for the applied indications and there is an unmet medical need in India. Further, the committee also noted that there is an ongoing Phase IV study in India. After detailed deliberation, the committee recommended for approval of additional indications based on the global clinical data with local clinical trial waiver.
14.	BIO/CT18/FF/2023/39893 Durvalumab Solution for Infusion 120 mg & 500 mg	M/s. AstraZeneca	The firm presented the proposal for approval of additional indications for the drug Durvalumab120 mg/2.4mL and 500mg/10mL solution for infusion (IMFINZI) based on global Phase-III study data with the request of local clinical trial waiver. After detailed deliberation, the committee noted that in POSEISON study significant benefit was not seen in the Asian population so that the committee did not consider the firm's request for waiver of local clinical trial for the proposed additional indication.
15.	79/Johnson/Phase IV/17-BD Daratumumab	M/s. J&J	The firm presented the clinical study report for drug product Daratumumab concentrate for solution for infusion 100 mg and 400 mg - DARZALEX titled "A prospective, single-arm, multicenter, pragmatic phase-iv trial investigating safety and effectiveness of DARZALEX (Daratumumab) in Indian subjects with relapsed and refractory

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			multiple myeloma, whose prior therapy included a Proteasome inhibitor and an Immunomodulatory agent" vide protocol No. 54767414MMY4008. The committee noted the results of the study. The firm is required to update the results of phase IV study in the package insert of the product.
16.	4-87/Merck/PAC-R-Avelumab/2021 – BD Avelumab	M/s.Merck Speciality Pvt. Ltd.	The firm presented the proposal to conduct Non Interventional Study (NIS) on the Bavencio (Avelumab concentrate for solution for infusion (Intravenous Infusion) in India vide protocol No. MS100070_0133, version 2.0 dated 08 Nov 2022. After detailed deliberation, the committee recommended the firm to conduct the study as per the presented protocol.
17.	BIO/CT04/FF/2023/40788 BP 13 (Filgrastim 300mcg/0.5mL solution for injection in PFS)	M/s. CuraTeQ	The firm presented the proposal to conduct Phase 1 study titled "A randomized, phase 1, double-blind, single-period, two-treatment, parallel, Multiple dose, balanced, comparative pharmacokinetic, pharmacodynamic, safety and immunogenicity assessment of BP13 (Filgrastim) 300 mcg/0.5 ml PFS with EU approved Neupogen 300 mcg/0.5 ml solution for injection in a pre-filled syringe Filgrastim in healthy adult male of BP13 (Filgrastim 300mcg/0.5ml solution for injection in a pre-filled syringe" vide protocol No. C1B03843/ BP13-102; V01 dated 29.11.2023. After detailed deliberation, the committee recommended the firm to conduct the Phase 1 study as per the presented protocol.
18.	BIO/CT04/FF/2023/40827 Polatuzumab Vedotin for Injection, 30mg/vial and 140 mg/via	M/s. Roche Products (India)	The firm presented the proposal to conduct Phase IV clinical trial titled "A Phase IV, open label, study evaluating the safety and efficacy of polatuzumab vedotinin combination with Rituximab and CHP(R-CHP) in previously untreated adult patients with diffuse

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			large B-Cell Lymphoma (DLBCL)"vide protocol No: ML45360 version 1 dated 28 Nov 2023. After detailed deliberation, the committee recommended the firm to recalculate the sample size based on the SAEs reported in previous studies and to include more Government study sites. Accordingly, the firm should submit the revised protocol to CDSCO for further evaluation by the committee.
SND Division			
19.	SND/MA/23/000081 Ondansetron Extended Release Injectable Suspension 100mg/1ml	M/s. FTF Pharma Private Limited.	The firm presented their proposal for grant of permission to conduct Phase-III clinical trial of ondansetron extended release injectable suspension 100mg/ml (Additional Strength) along with Phase-I study results and Phase-III clinical trial protocol before the committee. The committee noted that another firm also submitted application for proposed ondansetron extended release injectable suspension 100mg/ml. After detailed deliberation, the committee opined that the firm should submit more scientific relevance and more clinical safety data to CDSCO for further review by the committee. Further, the committee also opined that the both proposals should be deliberated in same SEC meeting to take further necessary action.
20.	SND/IMP/23/000071 Osimertinib Tablets 40mg and 80 mg	M/s. AstraZeneca Pharma India Ltd.	The firm presented their proposal for grant of permission to import and marketing of Osimertinib tablets 40mg and 80 mg (additional Indication) along with Global Clinical Trial data before the committee. The firm has informed that the proposed drug Osimertinib tablets 40mg and 80 mg already approved on 29.05.2017, 03.08.2018 and 09.03.2021 for other indication.

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			The committee noted that the proposed indication not yet approved anywhere. After detailed deliberation, the committee opined that the firm should submit more scientific relevance and more clinical safety data to CDSCO for further review by the committee.
21.	SND/MA/23/000028 Abiraterone Acetate oral suspension 1000mg/5ml	M/s. BDR Pharmaceuticals Int. Pvt. Ltd.	In light of earlier SEC recommendation dated 28.03.2023 & 29.03.2023. The firm presented the Bioequivalence study report along with justification for waiver of Phase-III clinical trial before the committee. The firm has informed that the proposed drug formulation Abiraterone Acetate oral suspension 1000mg/5ml not yet approved anywhere. After detailed deliberation, the committee opined that the justification provided by the firm for waiver of clinical trial is not found adequately. Therefore, the firm should conduct Phase-III clinical trial for which firm should submit Phase-III clinical trial protocol to CDSCO for further review by the committee.