

Recommendations of the SEC (Oncology) made in its 07th/24 meeting held on 03.04.2024 & 04.04.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/16/24 Online Submission (41452) GME751 (Pembrolizumab) concentrate for solution for infusion 25 mg/mL (100 mg/vial)	M/s. Parexel	The firm presented Phase III clinical study protocol No. CGME751A12301, version 1.0 dated 24 July 2023. After detailed deliberation, the committee recommended that the firm should submit early Phase safety data for further review by the committee and the firm should increase the number of government sites.
2.	CT/137/22 Online Submission (31487) Adjuvant Imlunestrant vs Standard Adjuvant	M/s. Eli Lilly	The firm presented protocol amendment (d) dated 05 Feb 2024 and India ICF V7.0 dated 21 Feb 2024 protocol No. J2J-MC-JZLH. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/37/22 Online Submission (31611) NBTXR3	M/s. PRA	The firm presented protocol amendment 4 version 5.0 dated 12 Feb 2024 protocol No. NANORAY-312. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/36/24 Online Submission (42264) Ribociclib (LEE011)	M/s. Novartis	The firm presented Phase IV clinical study protocol No. CLEE011A2412B version number 00 dated 19 Nov 2021 After detailed deliberation, the committee recommended for grant of permission to conduct the trial.
5.	CT/38/24 Online Submission (42326) MK-2870	M/s. MSD	The firm presented Phase III clinical study protocol No. MK-2870-010 version 00 dated 08 Nov 2023. After detailed deliberation, the committee recommended that the firm should submit more clarification for inclusion criteria for further review by the committee.
6.	CT/40/24 Online Submission (42322) BAT3306	M/s. IQVIA	The firm presented Phase I/III clinical study protocol No. BAT-3306-002-CR, version 1.0 dated 19 Dec 2023. After detailed deliberation, the committee

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			opined no early Phase data is available therefore, the applicant should submit fresh application with early phase data. Accordingly, the proposal cannot be considered.
7.	CT/42/24 Online Submission (42349) Zanidatamab (also known as ZW25 and JZP598)	M/s. PPD	The firm presented Phase III clinical study protocol No. JZP598-302-01, amendment 1 dated 20 Oct 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial.
8.	CT/29/18 Online Submission (31734) Osimertinib	M/s. AstraZeneca	The firm presented protocol amendment version 5.0 dated 03 Nov 2023 protocol No. D5160C00048. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
9.	CT/44/24 Online Submission (42441) Alnuctamab (BMS-986349/CC- 93269)	M/s. BMS	The firm presented Phase III clinical study protocol No. CA058-1019 version 2.0 dated 13 Oct 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial.
Biological Division			
10.	BIO/CT18/FF/2023/4 1177 Toripalimab 240mg solution for infusion	M/s. Dr. Reddy's Laboratories Limited	The firm presented the proposal for grant of permission to import and market Toripalimab 240mg solution for infusion for the following indications 1. In combination with cisplatin and gemcitabine, for first-line treatment of adults with metastatic or with recurrent locally advanced nasopharyngeal carcinoma (NPC). 2. As a single agent for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy with local Phase III clinical trial waiver. The committee noted that the proposed drug Toripalimab granted an orphan drug designation for the treatment of nasopharyngeal cancer by the US FDA & EMA and approved in China & USA for the proposed indications based on Phase II & Phase III trials conducted. There is

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			<p>an unmet medical need for recurrent locally advanced / metastatic nasopharyngeal carcinoma (RM-NPC) in India.</p> <p>After detailed deliberation, the committee recommended for grant of permission to import and market the drug with waiver of local Phase III clinical trial with condition to conduct Phase IV clinical trial in India. Accordingly, Phase IV clinical trial protocol should be submitted by firm within 3 months from grant of marketing authorization.</p>
11.	<p>BIO/CT18/FF/2023/4 0741</p> <p>Durvalumab 120mg/2.4ml and 500mg/10ml solution for infusion</p>	M/s. Astra Zeneca	<p>The firm presented the proposal for approval of additional indication for Durvalumab 120mg/2.4ml and 500mg/10ml solution for infusion (IMFINZI) i.e., “Durvalumab in combination with Tremelimumab for the treatment of patients with unresectable hepatocellular carcinoma (uHCC)”.</p> <p>The committee noted that the firm already holding permission for the indication of combination drug treatment i.e., "Tremelimumab in combination with Durvalumab for the treatment of patients with unresectable hepatocellular carcinoma (uHCC)".</p> <p>After detailed deliberation, the committee recommended for the approval of proposed additional indication subject to the condition that “Indication should be revised by including as first line therapy for Child-Pugh class A patients”. Accordingly, revised application shall be submitted to CDSCO for further process.</p>
12.	<p>BIO/CT18/FF/2023/4 0657</p> <p>Elranatamab Solution for Injection (40mg/mL)</p>	M/s. Pfizer Products India Private Limited	<p>The firm presented the proposal for grant of permission to import and market of Elranatamab solution for injection 44 mg/1.1 mL (40 mg/mL) and 76 mg/1.9 mL(40 mg/mL) along with request for local clinical trial waiver. The drug is indicated as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome</p>

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			<p>inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.</p> <p>The committee noted that the drug has an accelerated approval (conditional approval) in USFDA for proposed indication based on Phase II clinical trial data and the trial is ongoing.</p> <p>After detailed deliberation, the committee did not consider the firm's request for waiver of local clinical trial for grant of permission to import and market Elranatamab solution for injection.</p>
13.	<p>BIO/CT04/FF/2024/41381</p> <p>Trastuzumab Emtansine Powder for concentrate for solution for Infusion 100mg/vial & 160 mg/vial</p>	<p>M/s. Intas Pharmaceutical Ltd.</p>	<p>The firm presented the proposal to conduct Phase III clinical trial study titled "A prospective, randomized, open-label, parallel group, active-controlled, multicenter, Phase III study to evaluate the efficacy, safety, immunogenicity and pharmacokinetics of proposed Trastuzumab Emtansine biosimilar compared with Kadcyla® in HER2-Positive Unresectable Locally Advanced or Metastatic Breast Cancer patients who have received prior treatment with Trastuzumab and a Taxane" vide protocol No. 0198-23 version No.: 1.1, dated 03-Jan-2024.</p> <p>After detailed deliberation, the committee recommended to conduct the Phase III clinical trial as per the protocol presented by the firm.</p>
14.	<p>BIO/CT04/FF/2023/40241</p> <p>Trastuzumab deruxtecan concentrate solution for infusion 100 mg/5 ml</p>	<p>M/s. Astra Zeneca</p>	<p>The firm presented the proposal for permission to conduct Phase-IV study titled as "A prospective, multi-center, Phase IV, single arm study to assess the safety of Trastuzumab Deruxtecan, an anti-HER2- antibody drug conjugate in Indian patients with unresectable or metastatic HER2-Positive Breast Cancer who have received a prior anti-HER2-Based Regimen (STRIDE)" vide protocol No. D9673L00012, version 1.0 dated 13 Sep 2023.</p> <p>After detailed deliberation, the committee recommended to conduct the study as per</p>

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			the protocol presented by the firm.
BA/BEDivision			
15.	File No. 12-09/ 2024/BA-BE/ MISC-12/DC BABE/CT05/FF/2023 /40852 Ruxolitinib ER Tablets 50mg	M/s. Lotus Labs Pvt. Ltd., Karnataka-560094	The firm presented the protocol No.: 5465-23 ver. 1.0 dated 31.10.2023 for the BA/BE study for export purpose only. After detailed deliberation, the committee recommended to conduct the comparative Bioavailability study as presented by the firm for export purpose only.
16.	File No. 12-09/ 2024/BA-BE/ MISC-21/DC BABE/CT05/FF/2023 /40425 Ruxolitinib Tablets 20mg	M/s. Alembic Pharmaceuticals Limited, Vadodara-390003	The firm presented Bioavailability study protocol No. 055-23 version No. 00 dated 27.10.2023 under fasting condition for export purpose only. After detailed deliberation, the committee recommended to conduct the comparative bioavailability study as presented by the firm subject to condition that one MD (Medical Oncology) should be part of study team.
SND Division			
17.	SND/MA/23/000061 Methotrexate Oral Solution 2mg/mL	M/s. Beta Drugs Limited	In light of earlier SEC recommendation dated 10/10/2023, the firm presented BE study report along with request for waiver of Phase-III clinical trial before the committee. After detailed deliberation, the committee opined that the firm should submit sufficient clinical data along with global approval status of the proposed formulation to CDSCO for further review by the committee.
18.	SND-12012/2024- eoffice Olaparib Film Coated Tablets 100mg & 150mg	M/s. Astrazeneca Pharma Limited	In light of earlier SEC recommendation dated 23/02/2023, the firm presented the proposal for Phase IV CT waiver of Olaparib film coated tablet 100mg & 150mg before the committee. This office has already granted permission to the firm vide permission No. IMP/SND/23/000084 dated 17.11.2023 with Phase-III clinical trial waiver subject to condition that firm should conduct Phase-IV clinical trial study on 300 populations. After detailed deliberation, the committee

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			<p>opined that the waiver of Phase IV clinical trial cannot be considered and can be conducted on statistically significant population.</p>
19.	<p>SND/MA/23/000316</p> <p>Lenalidomide Capsules 20mg (Additional Strength)</p>	<p>M/s. Dr.Reddy's Labs Limited</p>	<p>The firm presented the proposal for manufacturing and marketing permission for Lenalidomide capsules 20mg (additional strength) along with justification for waiver of Phase-III CT with Bioequivalence study report of Lenalidomide capsules 25mg before the committee.</p> <p>The firm has informed that the proposed formulation strength 5mg 10 mg, 15mg and 25 mg of Lenalidomide Capsules 20mg are already approved by CDSCO since year 2007 in the country. The proposed strength 20 mg of Lenalidomide capsules is only for dose titration purpose only.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market Lenalidomide capsules 20mg (additional strength) with Phase-III clinical trial waiver.</p>
20.	<p>SND/MA/23/000081</p> <p>Ondansetron Extended Release Injectable Suspension 100 mg/1 mL</p>	<p>M/s. FTF Pharma Private Limited</p>	<p>In light of earlier SEC recommendation dated 07/02/2024 & 08/02/2024, the firm presented Phase III clinical trial of Ondansetron extended release injectable suspension 100 mg/ml (Additional dosage form) (protocol no. 004/ACRS/CINV/FTF/2023 ver. 1.0 dated 01.11.2023) along with Phase I study results & clinical safety data.</p> <p>After detailed deliberation, the committee opined that the firm should submit the proper cohort characterization & stratification of each group of patient w.r.t. highly emetogenic chemotherapy & moderately emetogenic chemotherapy and their cycles. Therefore, the firm should submit revised Phase-III CT protocol to CDSCO for further review by the committee.</p>