

Recommendations of the SEC (Oncology) made in its 16th/24 meeting held on 07.08.2024 & 08.08.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/108/23 Online Submission (33373) Volrustomig (MEDI 5752) Lyophilized Powder	M/s. AstraZeneca	The firm presented protocol amendment version 3.0 dated 23 May 2024, protocol no. D7984C00002. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/97/21 Online Submission (33432) Amivantamab and Lazertinib	M/s. J&J	The firm presented protocol amendment 7 dated 05 April 2024, protocol no. 61186372NSC3002. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/145/23 Online Submission (33514) Volrustomig (MEDI 5752)	M/s. AstraZeneca	The firm presented protocol amendment version 2.0 dated 21 May 2024, protocol no. D798EC00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/81/21 Online Submission (33641) GALINPEPIMUT-S	M/s. PPD Pharmaceutical	The firm presented protocol amendment version 5.0 dated 10 April 2024, protocol no. SLSG18-301. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
5.	CT/85/24 Online Submission (44054) Golcadomide (BMS-986369/CC - 99282)	M/s. Bristol-Myers Squibb India Pvt. Ltd.	The firm presented phase 3 clinical trial protocol no. CA0073-1020, version 01 dated 15 February 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the phase 3 clinical trial as presented by the firm.
6.	CT/151/22 Online Submission (34938) Hydrogen Peroxide	M/s. Prorelix Services LLP	The firm did not turn up for the Presentation.
7.	CT/50/24 Online Submission (42642) LEE011	M/s. Novartis Healthcare Private Limited	The firm did not turn up for the Presentation.

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8.	CT/53/24 Online Submission (42731) FYB206 (Pembrolizumab)	M/s. InVentiv International Pharma Services Pvt. Ltd.	In light of earlier SEC recommendation 02.05.2024, the firm presented Phase III clinical study protocol no. FYB206-C3-02, version 2.0 dated 22 February 2024. After detailed deliberation, the committee reiterate that the firm should submit preclinical study data for further review by the committee.
9.	CT/38/24 Online Submission (42326) MK-2870 (SKB264)	M/s. MSD Pharmaceuticals Private Limited	The firm presented phase 3 clinical trial protocol no. MK-2870-010, version 00, dated 08 Nov 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the phase 3 clinical trial as presented by the firm.
Biological Division			
10.	4-25/Roche/PAC-R- Atezolizumab-2022- BD (Diary no E-32557) Atezolizumab injection 1200mg/20ml and 840mg/14mLvial	M/s. Roche	In light of the SEC recommendations dated 07.02.2024 & 08.02.2024 the firm presented the required data as required by SEC for modification of indication of the drug Atezolizumab injection (1200mg/20ml and 840/40rng vials) in line with indication approved by EMA. After detailed deliberation, the committee recommended for approval of modified indication of the drug inline with EU SmPC. Further the firm should submit the chronology of regulatory approvals obtained from EMA and USFDA for the applied indications to CDSCO for review and approval of modified indication applied by the firm.
11.	BIO/CT18/FF/2024/4 3082 Pembrolizumab Injection 100mg/4ml (25mg/ml solution in a single vial)	M/s. MSD	The firm presented the proposal for approval of additional indications of Non-small cell lung carcinoma (monotherapy and combination therapy) along with results of clinical trial conducted globally and safety data of ongoing Phase IV trial in India with request for Phase III and Phase IV study waiver. The committee noted that the Phase IV study is ongoing and further there is no safety data available in Indian populations for the proposed additional indications.

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			After detailed deliberation, the committee did not consider the firm proposal for grant of additional indications with waiver of Phase III and IV clinical trial.
12.	BIO/CT18/FF/2024/4 1456 Durvalumab 120 mg/2.4 mL and 500 mg/10 mL solution for infusion	M/s. Astra Zeneca	<p>In light of the earlier SEC recommendations dated 19th & 20th March 2024, firm presented the required Asian & Indian subset analysis data along with results of Phase-IV study for approval for additional indication i.e. “Durvalumab (IMFINZI) in combination with chemotherapy as neoadjuvant treatment, followed by IMFINZI as monotherapy after surgery, is indicated for the treatment of patients with resectable (tumours \geq 4 cm and/or node positive) NSCLC and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.”</p> <p>The Committee noted that proposed additional indication is approved in UK, Switzerland & Taiwan. The committee further noted that local phase IV study in the approved indication (unresectable non-small cell lung cancer) has been already completed by the firm.</p> <p>After detailed deliberation, the committee recommended for approval of proposed additional indication with condition that the firm shall conduct PMS study in the proposed indication in India. Accordingly, protocol for PMS study shall be submitted within 03 months of approval of additional indication.</p>
BA/BE Division			
13.	BABE/CT05/FF/2024 /42538 Dabrafenib Capsule 75 mg	M/s. Apotex Research Private Limited	<p>The firm presented the protocol No. 3504US-IMCP-DFB1310-FA Version No. 00 Protocol Date 09-FEB-2024.</p> <p>After detailed deliberation, the committee recommended for grant of permission for the conduct of the study for export purpose only.</p>

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SND Division			
14.	SND-16011(11)/94/2024-eoffice Olaparib Tablets 100mg & 150mg	M/s. Astrazeneca Private limited	The firm presented their proposal for updation in package insert of Olaparib Tablets 100mg & 150mg (Lynparza) with respect to proposed changes in the sections like undesirable effects, Pharmacological properties, and possible side effects in the prescribing information before the committee. After detailed deliberation, the Committee recommended for updation of proposed changes in the package insert.
15.	SND/IMP/24/000038 Olaparib film-coated Tablets 100mg and 150mg for additional indication	M/s. AstraZeneca Pharma India Limited	Firm did not turn up for presentation
New Drugs Division			
16.	ND/IMP/24/000030 Ivosidenib 250mg Film Coated Tablets	M/s. Servier India Pvt. Ltd.	The firm presented the proposal for import and market of the drug Ivosidenib 250mg film coated tablets along with justification for the Phase III Clinical trial waiver before the committee. After detailed deliberation, the committee recommended that the firm should submit subset analysis data for South-East Asian population and Caucasian population. Also, the firm needs to submit the data for unmet medical need of the drug and the percentage of IDH mutation in cholangiocarcinoma and survival benefits of the drug in IDH mutated cholangiocarcinoma for the further consideration by the committee.
17.	ND/MA/23/000080 Tucatinib Tablets 150 mg	M/s. BDR Pharmaceuticals	In light of earlier SEC recommendation dated 30.05.2023, the firm has presented the BE study report, before the committee. After detailed deliberation, the committee considered the BE study results of Tucatinib Tablets 150mg. The committee also clarified to the firm

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			<p>that CT waiver was not granted as per the earlier recommendations of SEC dated 30.05.2023. Hence, the firm presented the justification for Clinical Trial waiver, before the committee.</p> <p>After detailed deliberation, the committee did not recommend the waiver of Phase III clinical trial, as there is no safety data in Indian population and also the subject drug does not fall under the category of Orphan drug in India.</p> <p>Accordingly, the firm should submit the Phase III clinical trial protocol before the committee for further consideration.</p>