

Recommendations of the SEC (Oncology) made in its 18th/25 meeting held on 28.05.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/68/20 Online Submission (38554) Amivantamab and Lazertinib	M/s Johnson & Johnson Pvt. Ltd	The firm presented protocol amendment 5 dated 11 March 2025 protocol no. 73841937NSC3003. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/115/23 Online Submission (38798) Capivasertib (AZD5363) film-coated tablet 160mg Capivasertib (AZD5363) film-coated tablet 200mg	M/s AstraZeneca Pharma India Limited	The firm presented protocol amendment 6 version 7.0 dated 20 March 2025 protocol no. D361DC00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/38/25 Online Submission (49020) BMS-986489 FDC (BMS-986012+Nivolumab)	M/s Bristol-Myers Squibb India Pvt. Ltd	The firm presented phase III clinical study protocol no. CA245-0001 version 1.0 dated 20 August 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
4.	CT/131/24 Online Submission (38943) Rilvegostomig (AZD2936)concentrate for solution for infusion 50 mg/mL (750mg/vial)	M/s AstraZeneca Pharma India Limited	The firm presented protocol amendment 3.0 dated 12 March 2025 protocol no. D702BC00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
5.	CT/132/24 Online Submission (38946) Rilvegostomig (AZD2936)concentrate for solution for infusion 50 mg/mL (750mg/vial)	M/s AstraZeneca Pharma India Limited	The firm presented protocol amendment version 3.0 dated 12 March 2025 protocol no. D702FC00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.

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6.	CT/44/25 Online Submission (49298) Azurity Cabozantinib Tablets	M/s CBCC Global Research LLP	The firm presented phase 2/3 clinical study protocol no. AZ-08131-7300-004 version 1.0 dated 23 April 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition <ol style="list-style-type: none"> 1. PI shall be Medical Oncologist only. 2. More geographically distributed government sites shall be included in the study.
7.	CT/46/25 Online Submission (49192) Envafolelimab injection 200mg/1ml.	M/s Glenmark Pharmaceuticals Ltd.	The firm presented phase III clinical study protocol no. GSP 401-302 version 1.0 dated 21 April 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. with condition that firm should submit global data US and Japan with pooled analysis and sub-group analysis to CDSCO. Dr. Kaushal Kalra didn't participated.
8.	CT/153/23 Online Submission (39075) Repotrectinib (BMS-986472,TPX-0005)	M/s Bristol-Myers Squibb India Pvt. Ltd	The firm presented protocol amendment 2 dated 13 Feb 2025 protocol no. CA127-1030. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. The firm shall submit other regulatory approval to CDSCO.