

Recommendations of the SEC (Oncology) made in its 14th/25 meeting held on 29.04.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/73/23 Online Submission (38305) Pembrolizumab200mg +Vibostolimab200mg	MSD Pharmaceuticals Private Limited	The firm presented protocol amendment 06 dated 29 January 2025 protocol no. 003. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/28/25 Online Submission (48484) Adagrasib	M/s Bristol-Myers Squibb India Pvt. Ltd	The firm presented phase III clinical study Protocol No.: CA2390004 original protocol dated 25-SEP-2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the PI Shall be Medical Oncologist only. Dr. Kaushal Kalra didn't participate.
3.	CT/30/25 Online Submission (48530) Trastuzumab Deruxtecan	M/s IQVIA RDS (India) Private Limited	The firm presented phase III clinical study Protocol No.: DS8201-772 Version No. 3.0 dated 04-DEC-2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the PI Shall be Medical Oncologist only. Dr. Kaushal Kalra didn't participate.
4.	CT/137/23 Online Submission (38355) Datopotamab deruxtecan (DS-1062a) 100 mg/vial Durvalumab (MEDI4736) 500mg/vial	M/s. AstraZeneca Pharma India Limite	The firm presented Protocol Amendment version 4.0 dated 13 February 2025 Protocol No: D7630C00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
5.	CT/36/22 Online Submission (37746) Selpercatinib	M/s Eli Lilly And Company	The firm presented protocol amendment (i) dated 16-Jan-2025 protocol no. J2G-MC-JZJX. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.

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6.	CT/96/24 Online Submission (38374) Datopotamab Deruxtecan and Osimertinib	PAREXEL International Clinical Research Private Limited	The firm presented protocol amendment version 2.0, dated 03-July-2024 and protocol amendment version 3.0, dated 07-February-2025 protocol no. D516KC00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
7.	CT/111/23 Online Submission (38384) Daratumumab	M/s Spectrum Clinical Research Pvt. Ltd	The firm presented Protocol Version 3 dated 18 November 2024 and Increase in number of subjects from India 80 to 125 protocol no. BCD-264-2IDARVIVA. After detailed deliberation, the committee recommended for approval of protocol amendment and increase in number of subjects from 80 to 125 in India as presented by the firm.
8.	CT/89/21 Online Submission (38385) Lutetium (177Lu) edotreotide solution for infusion	M/s PSI CRO Pharma Pvt Ltd	The firm presented protocol amendment version 5.0 dated 14 February 2025 protocol no. DP-1111-02CT. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
9.	CT/31/25 Online Submission (47641) Adagrasib	M/s Pharmaceutical Research Associates India Private Limited	The firm presented phase III clinical study protocol no. 849-007 version 9.0 dated 24 September 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the PI Shall be Medical Oncologist only.
10.	CT/23/22 Online Submission (38420) Durvalumab (MEDI4736)+ Tremelimumab	M/s AstraZeneca Pharma India Limited	The firm presented Protocol Amendment version 3.0, dated 18 Dec 2024 protocol no. D910VC00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. Dr. Kaushal Kalra didn't participate