

**Recommendations of the SEC (Oncology) made in its 21<sup>th</sup>/25 meeting held on 25.06.2025 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/48/24 Online Submission (39441)  MK-2870	M/s MSD Pharmaceuticals Private Limited,	The firm presented protocol amendment 03 dated 21 April 2025 protocol no. 009.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.  Dr. Kaushal Kalra didn't participate.
2.	CT/67/25 Online Submission (49781)  GME751 (pembrolizumab) concentrate for solution for infusion 25 mg/mL (100 mg/vial)	M/s PAREXEL International Clinical Research Private Limited	The firm presented phase IIIb clinical study Protocol No.: CGME751A12302 Version no. 4.0 dated 28-APR-2025.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/68/25 Online Submission (49790)  Olverembatinib (HQP1351)	M/s IQVIA RDS (India) Private Limited	The firm presented phase III clinical study Protocol no.: HQP1351CG301 Version no. 3.1 dated 22-APR-2025.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
4.	CT/69/25 Online Submission (49787)  Lisafoclax (APG- 2575)	M/s IQVIA RDS (India) Private Limited	The firm presented phase III clinical study Protocol no.: APG2575CG301 Version no. 2.1 GL dated 29-MAR-2025.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
5.	CT/72/25 Online Submission (49971)  Leuprolide acetate for injectable suspension, 30 mg	M/s CBCC Global Research LLP	The firm presented phase III clinical study Protocol Number: TOL2506A-EXT, Version no. 2.0 dated 13/Feb/2023.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.