

**Recommendations of the SEC (Oncology) made in its 21<sup>th</sup>/24 meeting held on 23.10.2024 at CDSCO (HQ), New Delhi:**

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	GCT/PostAppr/2024/34530 Online Submission (34530)  (Savolitinib)	M/s. Fortrea	The firm presented protocol amendment version 5.0 dated 28 June 2024 protocol no. D5086C00001.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	GCT/CT04/FF/2024/45378 Online Submission (45378)  Enfortumab Vedotin	M/s. Klinera	The firm has withdrawn the application.
3.	GCT/CT04/FF/2024/45486 Online Submission (45486)  GIM-122	M/s. CBCC	The firm presented phase ½ clinical study protocol no. GIM122-CT01 version 3/India 1, 16 September 2024.  After detailed deliberation, the committee opined that applicant shall submit following for further review by the committee: 1.Complete Pharmacodynamics study data 2. Criteria for dose selection and dose fixing (escalation and de-escalation) 3. Median duration for response 4. PI shall be medical oncologist only
4.	GCT/PostAppr/2024/35183 Online Submission (35183)  Datopotamab Deruxtecan (DATO-DXT, DS-106)	M/s. AstraZeneca	The firm presented protocol amendment 3.0 version 4.0 dated 30 July 2024 protocol no. D926PC00001.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
5.	GCT/PostAppr/2024/35144 Online Submission (35144)  Elranatamab 40 mg/ml Solution for Injection	M/s. Pfizer	The firm presented protocol amendment 5 dated 10 June 2024 protocol no. C1071007.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.

<b>S. No.</b>	<b>File Name &amp; Drug Name, Strength</b>	<b>Firm Name</b>	<b>Recommendations</b>
6.	GCT/PostAppr/2024/35168 Online Submission (35168)  Acalabrutinib Capsule	M/s. Fortrea	The firm presented protocol amendment version 7.0 dated 29 May 2024 protocol no. ACE-LY-312(D8227C00001)  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm
7.	GCT/PostAppr/2024/35043 Online Submission (35043)  Datopotamab Deruxtecan (DS-1062a) 100 mg/vial Durvalumab (MEDI4736) 500 mg/vial	M/s. Astrazeneca	The firm presented protocol amendment version 3.0 dated 22 July 2024 protocol no. D926QC00001.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.  Dr. Kaushal Kalra didn't participate.
8.	GCT/PostAppr/2024/34983 Online Submission (34983)  Datopotamab Deruxtecan (DS-1062a) 100 mg/vial Durvalumab (MEDI4736) 500mg/vial	M/s. Astrazeneca	The firm presented protocol amendment version 3.0 dated 09 July 2024 protocol no. D7630C00001.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.