Recommendations of the SEC (Oncology & Haematology) made in its 123rd meeting held on 28.04.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/CT/000090 Darolutamide	M/s. Bayer Ltd.	The firm didn't turn up for presentation.
2.	ND/IMP/21/000022 Gilteritinib 40mg film coated tablet	M/s. Astellas Pharma	In light of earlier SEC recommendation dated 16.06.2021 & 17.06.2021, the firm presented their proposal with justification for Phase IV clinical trial waiver before the committee. The committee noted that the drug is not yet approved in the country. After detailed deliberation, the committee reiterated its earlier recommendation dated 16.06.2021 & 17.06.2021. Further, the committee opined that the firm may present their proposal after approval of the drug in the country.
GCT Division			
3.	CT/95/19 Online Submission (14753) Selpercatinib	M/s. Eli Lilly	The firm presented protocol amendment 2G-MC-JZJB(e) dated 04 Nov 2021 before the committee. After detailed deliberation, the committee recommended for approval of the proposed amendment.
4.	CT/101/21 Online Submission (16096) Dabrafenib plus Trametinib	M/s. Novartis	The firm presented protocol amendment version 1.0 dated 08/11/2021 before the committee. After detailed deliberation, the committee recommended for approval of the proposed amendment.
5.	CT/75/21 Online Submission (14958) Marstacimab	M/s. Pfizer	The firm presented protocol amendment 1.0 dated 08/11/2021 before the committee. After detailed deliberation, the committee recommended for approval of the proposed amendment with condition that the applicant should submit DSMB interim safety report for 6 months.
6.	CT/26/22 Online Submission (30811)	M/s. Bioinnovat	In light of earlier SEC recommendation dated 12.04.2022, the firm presented their proposal before the committee.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Itolizumab (EG001)		After detailed deliberation, the committee recommended for grant of permission to conduct the trial with the following conditions- 1. The study should be initially conducted in 20 subjects (10 subjects from each arm) from India and applicant should submit their safety data for review by the committee for further continuation of the study. 2. All randomized subjects should be provided leukocyte reduced and irradiated blood components throughout the study and monitoring of cytokines and QuantiFERON-TB Gold (QFT) TB test should be included in protocol.