

Recommendations of the SEC (Oncology) made in its 4th/24 SEC meeting held on 21.02.2024 at CDSCO (HQ) New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/145/23 Online Submission (40513) Volrustomig (MEDI5752) Lyophilized product for concentrate for solution for infusion 250 mg (50mg/ML)	M/s. AstraZeneca	In light of earlier SEC recommendation dated 21.12.23 and 22.12.23, the firm presented phase III clinical study protocol No. D798EC00001, After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/162/21 Online Submission (27804) PD-332991 (Palbociclib)	M/s. Pfizer	In light of earlier SEC recommendation dated 29.11.23 and 30.11.23, the firm presented protocol amendment 7.0 dated 31 May 2023 protocol No. A5481092. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/92/22 Online Submission (29561) Teclistamab	M/s. J&J	In light of earlier SEC recommendation dated 21.12.23 and 22.12.23, the firm presented protocol amendment 3.0 dated 14 June 2023 protocol No. 64007957MMY3005. After detailed deliberation, the committee opined that due to significant drug related toxicity, the protocol amendment may not be considered at this stage and more justification is required to be submitted for further review of the committee.
BA/BE Division			
4.	File.No.12-09/2024 /BE-BE/MISC-12/DC BABE/CT05/FF/2023 /40852 Ruxolitinib ER Tablets 50mg	M/s. Lotus Labs Pvt. Ltd, Karnataka-560094	The firm presented their proposal along with the protocol (No.: 5465-23 ver. 1.0 dt. 31.10.2023) of the BA/BE study for export purpose only. After detail deliberation, the committee recommended to present more safety data of Ruxolitinib 50 mg tablet when administered as single dose on healthy human subjects. Accordingly, the firm should submit the above mentioned data for re-deliberation by the SEC.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
5.	ND/CT/23/000100 Asciminib film coated tablets 20 mg and 40mg	M/s. Novartis	The firm did not turn up for presentation.