

Recommendations of the SEC (Oncology &Haematology) made in its 130th meeting held on 05.08.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/138/21 Online Submission (28645) Crizanlizumab	M/s. Novartis	In light of earlier SEC recommendation dated 11 and 12 Nov 2021, the firm presented the phase IV clinical trial protocol with justification before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the trial with condition that the firm should provide the post-trial access to the trial subject(s) as per the New Drugs and Clinical Trial Rules, 2019.
2.	CT/99/20 Online Submission (15699) TrastuzumabDeruxtec an (T-DXd)	M/s. AstraZeneca	In light of earlier SEC recommendation dated 23.06.2022, the firm presented justification/rationale vis-a-vis patient safety for the proposed protocol Amendment version 3.0 dated 23-Nov-2021 to the protocol no. D967C00001 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
3.	CT/38/17 Online Submission (17001) PEGylated Factor VIII (BAX 855)	M/s. Baxalta Bioscience	The firm didn't turn up for presentation.
4.	CT/57/21 Online Submission (17644) Encorafenib (PF-07263896)	M/s. Pfizer	The firm presented the proposed protocol amendment 4 dated 28-Feb-2022 to the protocol no.C4221015, before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
5.	CT/28/19 Online Submission (18945) Osimertinib + Savolitinib	M/s. AstraZeneca	The firm presented the proposed protocol amendment Version 7 dated 26Apr2022 to the protocol no. D5084C00007 (the SAVANNAH study) before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
6.	CT/78/20 Online Submission (19132)	M/s. AstraZeneca	The firm presented the proposed protocol amendment 3.0 dated 09May2022 to the

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Osimertinib vs Savolitinib		<p>protocol no. D5084C00009 (Expedition Lead-In study) before the committee.</p> <p>After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.</p>
7.	CT/104/21 Online Submission (17622) LY348-4356	M/s. Eli Lilly	<p>The firm presented the proposed protocol Amendment (a), dated 08-Oct-2021 to the protocol no. J2J-OX-JZLC (EMBER-3), before the committee.</p> <p>After detailed deliberation, the committee opined that the firm should present the protocol with amendments with justification in details in upcoming SEC.</p>