

Recommendations of the SEC (Oncology & Hematology) made in its 162nd meeting held on 29.11.2023 & 30.11.2023 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/122/23 Online Submission (39848) Rilvegostomig (AZD2936) concentrate for solution for infusion, 750mg/vial (50 mg/mL)	M/s. AstraZeneca	The firm presented Phase III Clinical Study Protocol no. D7025C00001. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm "subject to the condition that they include surgical oncologist in the study team to confirm the criteria of surgical resectability".
2.	CT/113/23 Online Submission (39550) CC-220 (BMS-986382)	M/s. PPD	The firm presented Phase III Clinical Study Protocol no. CC-220-MM-002. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/112/23 Online Submission (39429) INAVO122	M/s. Roche Products	The firm presented Phase III Clinical Study Protocol no. WO44263. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
4.	CT/111/23 Online Submission (39541) BCD-264 - Daratumumab 20 mg/mL, concentrate for solution for infusion	M/s. Spectrum Clinical Research	The firm presented Phase III Clinical Study Protocol no. BCD-264-2/DARVIVA. After detailed deliberation, the committee opined that the firm should submit the revised protocol as considering the following: 1. Optional for pharmacokinetic study. 2. Inclusion/Exclusion criteria for Pharmacokinetic study. 3. Details about no. of subject, will be recruited for Pharmacokinetic study in India. 4. Informed Consent Form for Pk study. Accordingly, the firm should submit the revised protocol and other documents for further review by the committee.
5.	CT/109/23 Online Submission (39515) Talquetamab	M/s. Johnson & Johnson	The firm presented Phase III Clinical Study Protocol no. 64407564MMY3009. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.

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6.	CT/108/23 Online Submission (39490) Volrustomig (MEDI5752)/ Placebo Lyophilized powder for solution for infusion 250 mg/vial	M/s. AstraZeneca	The firm presented Phase III Clinical Study Protocol no. D7984C00002. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
7.	CT/119/23 Online Submission (39699) Pembrolizumab	M/s. Fortrea Development India	The firm presented Phase III Clinical Study Protocol no. SB27-3004. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
8.	CT/115/23 Online Submission (39544) Capivasertib (AZD5363) film-coated tablet 160mg or 200mg	M/s. AstraZeneca	The firm presented Phase 1b/III Clinical Study Protocol no. D361DC00001. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm subject to the condition that Phase-Ib part of the study will not be applicable in India.
9.	CT/155/22 Online Submission (27593) Pembrolizumab 200mg +Vibostolimab 200mg	M/s. MSD Pharmaceuticals	The firm presented protocol amendment Version 02 dated 15- March 2023, Protocol no. MK7684A. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
10.	CT/143/21 Online Submission (28087) Hydrogen Peroxide	M/s. IQVIA RDS	The firm presented protocol amendment Protocol Version 4.0 dated 22 January 2023, Protocol no. CCR5119. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
11.	CT/162/21 Online Submission (27804) PD-332991 (Palbociclib)	M/s. Pfizer Limited	The firm presented Protocol Amendment 7.0 dated 31 May 2023, Protocol no. A5481092. After detailed deliberation, the committee recommended that justification and rationale for proposed amendment need to be submitted for further review by the committee.
12.	CT/23/22 Online Submission (27951)	M/s. AstraZeneca	The firm presented Protocol Amendment Version 2.0 dated 19 June 2023, Protocol no. D910VC00001.

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	Durvalumab in Combination with Tremelimumab ± Lenvatinib		After detailed deliberation, the committee recommended that the firm should submit interim report of the ongoing trail before the committee for further consideration.
13.	CT/131/22 Online Submission (27990) PF-06741086 Marstacimab	M/s. Pfizer	The firm presented Protocol Amendment 1 dated 22March 2023, Protocol no. B7841008 After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
14.	CT/147/22 Online Submission (28110) Ianalumab (VAY736)	M/s. Novartis	The firm Presented the proposal for wavier for condition (1) and (2) of clinical trial permission vide CT-NOC: CT/147/22-DCG(I) dated 04.07.2023. (1) Protocol section 6.8.3 w.r.t Rescue therapies should be modified as per current guidelines for treatment of ITP. (2)Background therapy/Rescue medications, i.e., platelet transfusion, corticosteroids and IVIG, etc. should be provided free of cost to the trial subjects throughout the conduct of the study. After detailed deliberation, the committee recommended that the Condition no. (1) & (2) should be same as per previous recommendation in its meeting held on 08.06.2023.
15.	CT/171/21 Online Submission (28247) Entrectinib Versus Crizotinib	M/s. Roche	The firm presented Protocol Amendment version 5.0 dated 17 April 2023, Protocol no. MO41552. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
16.	CT/110/21 Online Submission (28336) Asciminib	M/s. Novartis	The firm presented Protocol Amendment version 02 dated 15May 2023, Protocol no. CABL001J12301 After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
17.	CT/75/21 Online Submission (28337) Marstacimab Prophylaxis	M/s. Pfizer	The firm presented Protocol Amendment 3 dated 11 July 2023, Protocol no. B7841007. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.

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18.	CT/25/20 Online Submission (28307) Alpelisib (BYL719)	M/s. Novartis	The firm presented Protocol Amendment version 02 dated 14 March 2023, Protocol no. CBYL719H12301. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
19.	CT/68/21 Online Submission (28370) PTG-300	M/s. JSS Medical Research	The firm presented Protocol Amendment no. 10 dated 06 July 2023, Protocol no. PTG-300-04. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
20.	CT/71/23 Online Submission (38023) VGA039	M/s. Inventiv International	The firm presented Phase Ia Clinical Study Protocol no. VGA039-CP001. After detailed deliberation, the committee recommended to submit phase-I (healthy subject) study report for further review by the committee.
FDC Division			
21.	FDC/MA/22/000258 Transdermal Liposomal Lotion product containing API of Ferrous BisGlycinate (Elemental Iron), Vitamin B12, Vitamin D3, Folic Acid	M/s. Murli Krishna Pharma Pvt. Ltd.	In light of earlier SEC recommendation dated 10.10.2023, the firm presented their proposal along with PK study protocol and revised Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for conducting the PK study. Further, the committee opined that the firm should submit revised Phase III clinical trial Protocol which should be scientifically structured along with supporting documents. Accordingly, the results of PK study & revised Phase III clinical trial Protocol should be presented before the committee.