

Recommendations of the SEC (Oncology & Haematology) made in its 141st meeting held on 19.01.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	12-01/22-DC (Pt-338) Enzalutamide	M/s. Mahamana Pandit Madan Mohan Malaviya Cancer Centre	The firm presented its proposal to conduct Phase III academic clinical trial before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the presented protocol.
2.	ND/CT/22/000096 Fosnetupitant 235 mg and Palonosetron 0.25 mg (Concentrate for solution for infusion)	M/s. Glenmark Pharmaceuticals Ltd.	The firm presented Phase IV clinical trial protocol (Protocol No. GPL/CT/2022/008/IV, version: 2.0 dated 07-Dec-2022 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial as per the submitted protocol.
SND Division			
3.	SND/MA/22/000269 Pemetrexed Injection 10mg/ml (Pack size 10ml, 50ml, 85ml and 100ml)	M/s Shilpa Medicare	The firm presented its proposal for manufacturing and marketing of Pemetrexed injection 10 mg/ml (pack size 10 ml, 50 ml, 85 ml, and 100 ml) along with the rational of the proposed pack sizes. Committee noted that Pemetrexed Solution for injection 10 mg/mg (100 ml ready to use infusion bag) is already approved by CDSCO. After detailed deliberation, the committee recommended for grant of permission for Premetrexed Injection 10mg/ml (Pack size 10ml, 50ml, 85ml and 100ml) for already approved indication.
GCT Division			
4.	CT/162/21 Online Submission (19156) PALBOCICLIB (IBRANCE®)	M/s. Pfizer	The firm presented the proposed protocol Amendment 5 dated 26-Apr-2022 under the protocol no. A5481092 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
5.	CT/82/22 Online Submission (33480)	M/s. Novartis	The firm presented the proposed study protocol no. MBG453B12206B, version 00, dated 12-Nov-2021 before the

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	Sabatolimab (MBG453)		committee. After detailed deliberation, the committee clarified that there is no rationale for the proposed roll over study with respect to the in hand safety and efficacy data and hence did not recommend for the grant of permission to the proposed roll over study. The committee, however opined that post trial access to the study drug product may be provided as prescribed in the New Drugs and Clinical Trial Rules, 2019.
6.	CT/72/21 Online Submission (21472) Imetelstat (GRN163L)	M/s. Parexel	The firm presented the proposed protocol-GRN16LMYF3001, Amendment-2/ IND-2 dated 02-Aug-2022 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
7.	CT/143/22 Online Submission (34837) Ianalumab (VAY736)	M/s Novartis	The proposal was deferred for next meeting.
8.	CT/88/19 Online Submission (21943) PF-06741086 Prophylaxis	M/s. Pfizer	The firm presented the proposed protocol amendment 7 dated 24MAR2022 under the protocol no. B7841005 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
9.	CT/79/20 Online Submission (21970) Amivantamab and Carboplatin	M/s. J&J	The firm presented the proposed protocol-61186372NSC3001, Amendment-2, dated 12-Aug-2022 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
10.	CT/172/21 Online Submission (22331) Elranatamab (PF-06863135) versus lenalidomide	M/s. Pfizer	The firm presented the proposed protocol Amendment 2 dated 28-NOV-2022 under the protocol no. C1071007 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment with condition that there would be no increase in the number of subject from the initially approved number for the country.

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11.	CT/97/22 Online Submission (33424) Pertuzumab and Trastuzumab	M/s Roche	The firm presented the proposed study protocol no. MO43110, version 1.0, dated 02-FEB-2022 before the committee. After detailed deliberation, the committee opined that the applicant is required to submit complete toxicity data of combination drug therapy to CDSCO and for further review by the committee.
12.	CT/136/21 Online Submission (22375) Belantamab Mafodotin	M/s GSK	The firm presented the proposed protocol amendment version 01 dated 21-JAN-2022 under the protocol no. 209628 before the committee. After detailed deliberation, the committee did not recommend for approval of the proposal for increase in sample size from 15 to 20 considering high number of SAEs reported in the country.
13.	CT/137/22 Online Submission (34501) Imlunestrant vs standard adjuvant	M/s Eli lily	The firm presented the proposed study protocol no. J2J-MC-JZLH dated 15-Jun-2022 before the Committee. After detailed deliberation, the committee recommended for the grant of permission to conduct the proposed study with the following conditions: 1) The firm should actively monitor the adverse events specifically the skeleton related AEs and to submit such safety report to SEC/CDSCO for review on a yearly basis. 2) SAEs irrespective of its cause (i.e. PD) must be reported to CDSCO as per provisions of the New Drugs & Clinical Trial Rules, 2019.