Recommendations of the SEC (Oncology & Haematology) made in its 144th meeting held on 14.03.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/22/000063 Asciminib FCT 20mg & 40mg	M/s. Novartis Health Care Pvt. Ltd.	The proposal was deferred for next meeting.
2.	ND/CT/23/00005 Ferumoxytol Injection 30 mg/ml	M/s. Syngene International Ltd.	The firm presented its proposal for Phase-I clinical trial before the committee. The committee noted that the drug to be used in the proposed trial is not of Indian origin. After detailed deliberation, the committee recommended that the proposal submitted by firm could not be considered at present.
3.	ND/CT/21/000081 Capmatinib 150 mg & 200 mg Tablets	M/s. Novartis Healthcare	The proposal was deferred for next meeting.
4.	ND/MA/23/000004 Ferumoxytol Injection 510 mg	M/s. MSN Laboratories Pvt. Ltd.	The firm did not turn up for the presentation.
5.	ND/IMP/21/000022 Gilteritinib 40 mg Film Coated Tab	M/s. Astallas Pharma	The firm presented its proposal for Phase IV clinical trial waiver. Committee noted that firm has received import & marketing permission on 30-Dec-2022 for Gilteritinib 40mg film coated tab with condition that firm should conduct a Phase-IV clinical trial on at least 50 patients for which protocol should be submitted within 3 months of approval of the drug for review by the committee. After detailed deliberation, the committee recommended that the firm should submit the Phase IV clinical trial protocol with at least 50 subjects with uniform geographically distributed clinical trial sites. Accordingly, the firm should submit the Phase IV clinical trial protocol within 3

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			months to CDSCO for further consideration.
Biological Division			
6.	BIO/CT21/FF/2023/ 36021 Bevacizumab 100mg & 400mg	M/s. Reliance Life Sciences Pvt. Ltd	The proposal was deferred for next meeting.
7.	BIO/CT04/FF/2022/ 31172 Pertuzumab 420mg/14mLvial	M/s. Accutest Research Laboratories (I) Pvt. Ltd.	The proposal was deferred for next meeting.
8.	BIO/IMP/22/000075 Tremelimumab concentrate for solution for infusion	M/s. Astra Zeneca	The proposal was deferred for next meeting.
9.	4-10/Dr. Reddy's/PAC-R-Bevacizumab/2021-BD (Pt-1) Bevacizumab 100mg & 400mg	M/s. DRL	The proposal was deferred for next meeting.
10.	BIO/IMP/23/000003 Enfortumabvedotin 20mg & 30mg	M/s. Astellas Pharma India Pvt. Ltd.	The proposal was deferred for next meeting.
SND Division			
11.	SND/MA/23/000028 Abiraterone Acetate oral suspension 1000mg/5ml	M/s. BDR Pharmaceuticals Int. Pvt. Ltd.	The proposal was deferred for next meeting.
GCT Division			
12.	CT/141/22 Online Submission (34825) Ianalumab (VAY736)	M/s. Novartis	The applicant presented Phase III clinical trial protocol no CVAY736O12301, version 02 dated 29-09-2022 before the committee. The committee noted that the applicant has not conducted Phase II clinical trial with proposed indication; however, two

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			Phase III clinical trials on other indication are ongoing in India. The present trial will be conducted in patients with warm autoimmune hemolytic anemia and proposed for 16 subjects out of 90 subjects globally in the trial. After detailed deliberation, the committee recommended for grant of permission to conduct the trial with condition that the applicant should submit safety data of 45 global subjects (including 08 subjects from the country) for review by the committee and once the data is reviewed by the committee, trial might be continued in the country.
13.	CT/84/20 Online Submission (21202) Durvalumab	M/s. AstraZeneca	The applicant presented protocol amendment version 2.0 (amendment 1) dated 02-08-2022 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment with condition that all SAEs including death irrespective of its cause (death due to PD) should be reported to CDSCO as per provision of NDCT Rules 2019 by the PI & Sponsor.
14.	CT/42/22 Online Submission(21910) Durvalumab + Olaparib	M/s. Labcorp	The applicant presented protocol amendment version 5.0 dated 07-06-2022 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
15.	CT/143/22 Online Submission(34837) Ianalumab	M/s. Novartis	The applicant presented Phase III clinical trial protocol no CVAY736Q12301 before the committee. The committee noted that the applicant has not conducted Phase II trial with proposed indication; however, two Phase III trials with other indications are ongoing in India. The present trial will be conducted in patients with primary immune thrombocytopenia and proposed for 30 subjects out of 150 subjects globally in the trial. After detailed deliberation, the committee

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			recommended for grant of permission to conduct the trial with the condition that the applicant should submit safety data of 50 global subjects (including 15 subjects from the country) for review by the committee and once data is reviewed by the committee, the trial might be continued in the country.
16.	CT/32/22 Online Submission(22548) Durvalumab + Olaparb	M/s. Labcorp	The applicant presented protocol amendment version 5.0 dated 09-12-2021 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
17.	CT/41/22 Online Submission(23175) Paclitaxel - Carboplatin Oregovomab	M/s. Raptim Research	The applicant presented protocol amendment version 3.0 (Amendment 3) dated 20-02-2022 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
18.	CT/154/22 Online Submission(34879) ASP-1929 Cetuximab sarotalocan sodium	M/s. Rakuten Medical	The applicant has presented Phase III clinical trial protocol no ASP-1929-391, amendment 3.1 dated 10-06-2020, version 1.0 dated 07-11-2022 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the trial with condition that all SAEs including death irrespective of its cause (death due to PD) should be reported to CDSCO as per provision of NDCT Rules 2019 by the PI & Sponsor.