

Recommendations of the SEC (Oncology & Haematology) made in its 140th meeting held on 10.01.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/22/000166 Relugolix Tablets 120mg	M/s Alkem Laboratories Ltd.	The firm presented their proposal to conduct Bioequivalence study and justification for clinical trial waiver before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Bioequivalence study as per the presented protocol. The firm should submit Bioequivalence study report for further review by committee.
2.	ND/IMP/22/000063 Asciminib Tblets 20 mg and 40 mg	M/s Novartis Healthcare Pvt. Ltd.	The firm didn't turn up for presentation.
Biological Division			
3.	BIO/MA/20/000041 Trastuzumab	M/s Hetero Biopharma Ltd.	In light of earlier recommendation of SEC dated 15.09.2020 & 16.09.2020, the firm presented results of completed Phase III clinical study before the committee. After detailed deliberation, the committee noted the results of the study. (Dr. Chinmoy K Bose did not participate during deliberation).
4.	4-30/DRL/PAC-R- Trastuzumab/ 2022-BD Trastuzumab	M/s Dr. Reddy's Laboratories	In light of earlier recommendation of SEC dated 07.02.2018, the firm presented results of Phase IV clinical study before the committee. After detailed deliberation, the committee noted the results of the study.
5.	BIO/IMP/22/000082 Nivolumab	M/s Bristol-Myers Squibb India Pvt. Ltd.	The firm presented their proposal for additional indication "Nivolumab indicated for treatment of patients with advanced renal cell carcinoma (RCC) in combination with Cabozantinib" before the committee. The committee noted that there is no data available on Indian patients in proposed indication for the proposed combination regimen.

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			After detailed deliberation, the committee recommended that the firm should conduct local clinical trial to generate safety data in Indian population.
6.	4-101/Reliance/PAC-R-Interferon alfa 2b/2020-BD Interferon Alfa 2b injection	M/s Reliance Life Sciences Pvt. Ltd.	The firm didn't turn up for the presentation.
7.	BIO/MA/22/000104 Denosumab 60 mg/ml injection	M/s Enzene Biosciences Ltd.	<p>The firm presented their proposal for following additional indications with justification of extrapolation of indications before the committee.</p> <ol style="list-style-type: none"> 1. Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer. 2. Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. <p>After detailed deliberation, the committee recommended that firm should submit data of ongoing Phase-IV study in India for further consideration of extrapolation of indications.</p>
SND Division			
8.	SND/MA/20/000016 Pegaspargase powder for solution for injection/750U	M/s Servier India	<p>The firm presented their proposal of updated package insert for "Pegaspargase powder for solution for injection/ infusion 750U" with details of proposed changes in Version No.03 before the committee.</p> <p>After detailed deliberation, the committee recommended for approval of proposed package insert for "Pegaspargase powder for solution for injection/ infusion 750U, Version No. 03" as presented by the firm.</p>
9.	SND/MA/22/000313 Micronized Purified	M/s Seriver India	The firm presented their proposal for manufacture and marketing permission of Purified Flavonoid Fraction 500mg Tablets (Additional Strength) for the indication as "1. Treatment of symptoms

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	Flavonoid Fraction 500mg Tablets		<i>related to venolymphatic insufficiency (heavy legs, pain, restless leg syndrome), 2. Treatment of functional symptoms related to hemorrhoidal attack”</i> before the committee. After detailed deliberation, the committee recommended that the proposal should be presented in presence of general surgeon or vascular surgeon or CTVS surgeon in next SEC (Oncology) meeting.
BA/BE Division			
10.	12-09/2022/BA-BE/Misc-18/DC Palbociclib/ Letrozole 75mg/2.5mg film coated tablets	M/s Clantha Research Limited, Ahmedabad - 382210	The firm presented their protocol for BA/BE study for export purpose. After detailed deliberation the committee recommended for grant of permission to conduct the proposed BA/BE study with the condition that Oncologist should be a part of clinical trial team.
GCT Division			
11.	CT/162/21 Online Submission (19156) Palbociclib (IBRANCE®)	M/s. Pfizer	The proposal was deferred for next meeting.
12.	CT/82/22 Online Submission (33480) Sabatolimab (MBG453)	M/s. Novartis	The proposal was deferred for next meeting.
13.	CT/72/21 Online Submission (21472) Imetelstat (GRN163L)	M/s. Parexel	The proposal was deferred for next meeting.
14.	CT/88/19 Online Submission (21943)	M/s. Pfizer	The proposal was deferred for next meeting.

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	PF-06741086 Prophylaxis		
15.	CT/79/20 Online Submission (21970) Amivantamab and Carboplatin	M/s. J&J	The proposal was deferred for next meeting.
16.	CT/172/21 Online Submission (22331) Elranatamab (PF-06863135) versus Lenalidomide	M/s. Pfizer	The proposal was deferred for next meeting.
17.	CT/78/22 Online Submission (33350) FS118	M/s. Star Genomics	In light of earlier SEC recommendation dated 11.11.2022, the applicant presented Phase 1 and Phase 2 clinical data along with approval letters from concerned regulatory authorities (USFDA and EU countries) and changes introduced from version 1 to version 2 of proposed Phase II protocol FS118-21201. After detailed deliberation, the committee recommended for grant permission to conduct the proposed Phase II study.
18.	CT/124/22 Online Submission (34341) CABL001J12302; Version number: 00 24.05.2022	M/s. Novartis	The applicant presented Phase IIIb clinical trial protocol no. CABL001J12302 version: 00(original protocol) dated 24.05.2022 before the committee. After detailed deliberation, the committee opined that the applicant should submit the following:- 1. Justification for proposing the Phase of study as Phase IIIb when the primary objective of the study is safety. 2. Applicant should submit recommendation letter from German and French health regulatory agency for the proposed study as applicant informed that the proposed Phase IIIb study was recommended by German and French

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			health regulatory with primary objective as safety.
Additional Agenda			
19.	SND/CT/22/000072 Ketamine Hydrochloride injection 50mg/ml (Subcutaneous injection)	M/s. Themis Medicare Ltd.	<p>The firm presented their proposal of Phase III Clinical Trial study protocol to evaluate the safety and efficacy of Ketamine Hydrochloride Injection 50 mg/ml with new route of administration (SC) for pain management in cancer patients before the committee.</p> <p>After detailed deliberation the committee opined that in-light of abuse potential and chronic systemic toxicity involved (hepatic toxicity, neurological toxicity etc.), it is required to refer to the recommendation of other SEC committee i.e. SEC (Neurology) in which the firm presented another Phase III CT protocol for the applied drug product for other indication.</p> <p>Further, the committee also opined that Medical Oncologist should be involved in the investigator panel of the proposed trial.</p> <p>In view of above, the committee recommended that the recommendation of above mentioned SEC and outcome of the said clinical study along with revised investigator panel should be placed for further consideration by the committee.</p>