

Recommendations of the SEC (Oncology & Haematology) made in its 149th meeting held on 30.05.2023 at CDSCO HQ New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	12-07/2015-DC (Pt-PMS) Ibrutinib capsules 140mg	M/s. Johnson & Johnson	The firm presented the proposal for protocol amendment vide protocol version 2.0 dated 20-Oct-2022 before the committee. After detailed deliberation, the committee recommended for grant of approval for the protocol amendment as presented by the firm.
2.	ND/MA/22/000144 Relugolix Tablets 120mg	M/s Zydus Lifesciences Ltd.	In light of earlier SEC recommendation, dated 09.12.2022, the firm presented its proposal for manufacture and marketing of the drug Relugolix 120 mg tablets indicated for treatment of adult patients with advanced prostate cancer along with BE study report and justification for local clinical trial waiver. After detailed deliberation, the committee recommended that the firm should present the innovator's safety and efficacy data for further consideration.
3.	ND/CT21/FF/2023/3723 Tucatinib Tablet 50mg & 150mg	M/s. B.D.R Phar. Inter. Pvt. Ltd.	The firm presented the proposal to conduct bioequivalence study and justification for clinical trial waiver before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the Bioequivalence study as per the presented protocol. The firm should submit bioequivalence study report to CDSCO for further review by the committee.
4.	F. No. 12-1/23-DC (Pt-95) Olanzapine	Dr. Sameer Bakshi, Professor, Dept. of Medical Oncology, Institute Rotary Cancer Hospital, AIIMS, New Delhi.	The Principal Investigator presented the proposal of clinical trial before the committee. After detailed deliberation, the committee recommended for grant of approval for the proposed clinical trial, subject to condition that AV recording should be done and there should be insurance coverage for compensation for clinical trial related SAE/injury for trial subjects participating in the study.

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SND Division			
5.	SND/MA/23/000054 Ferric Carboxymaltose Injection 50mg/ml	M/s. Dr. Reddy's Laboratories	The proposal was deferred for next SEC meeting.
GCT Division			
6.	CT/95/19 Online Submission (18331) Selpercatinib	M/s. Eli Lilly	<p>The firm presented the proposal for protocol amendment no.f dated 06-Apr - 2022; Study Protocol No. J2G-MC-JZJB before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of approval for the protocol amendment as presented by the firm.</p>
7.	CT/104/21 Online Submission (22800) LY3484356	M/s. Eli Lilly	<p>The firm presented the proposal for protocol amendment no. b dated 17-Aug-2022; Study Protocol No. J2G-MC-JZJB before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of approval for the protocol amendment as presented by the firm.</p>
8.	CT/75/21 Online Submission (23014) Marstacimab Prophylaxis	M/s. Pfizer	<p>In light of earlier SEC recommendations of meeting dated 28.03.2023 & 29.03.2023, the firm presented the details of all ongoing and completed trials conducted on IMP worldwide before the committee.</p> <p>After detailed deliberation, the committee recommended for the grant of approval for the proposed protocol amendment 2 dated 01-Dec-2022, study protocol no. B7841007 as presented.</p>
9.	CT/11/23 Online Submission (35893) TAR-200 + Cetrelimab	M/s. J&J	<p>The firm presented the proposal for Phase III clinical trial vide protocol no. 17000139BLC3002, amendment 1, dated 06-Dec-2022 before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission for the conduct of the proposed Phase III clinical trial as presented by the firm.</p>
10.	CT/19/23 Online Submission (36477)	M/s. PSI CRO	The firm presented the proposal for Phase III clinical trial vide protocol No. ELC-G-301, version 3.0, dated 11-Oct-2022

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	Gedatolisib Powder for Solution for infusion		before the committee. After detailed deliberation, the committee recommended for grant of permission for the conduct of the proposed Phase III clinical trial as presented by the firm.
11.	CT/79/22 Online Submission (25026) BCD-217 (Nurulimab +Prolgolimab)	M/s. IR Innovate Research	The firm presented the proposal for protocol amendment version no. 2 dated 31-Jan-2023; protocol No. BCD-217-2/OCTAVA before the committee. After detailed deliberation, the committee recommended for grant approval of the protocol amendment as presented by the firm.
12.	CT/39/22 Online Submission (25389) JDQ443	M/s. Novartis	The firm presented the proposal for protocol amendment no. JDQ443B12301 Version -02 dated 24 Oct 2022 before the committee. After detailed deliberation, the committee recommended to grant of approval to the protocol amendment as presented by the firm.
13.	CT/147/22 Online Submission (34864) VAY736 (Ianalumab)	M/s. Novartis	The proposal was deferred for next SEC meeting.
14.	CT/105/22 Online Submission (33987) Phesgo (Pertuzumab+ Trastuzumab)	M/s. Roche	The proposal was deferred for next SEC meeting.
15.	CT/13/23 Online Submission (35992) PZN-128	M/s. GCT Pharma Research	In light of earlier SEC recommendations of meeting dated 28.03.2023 & 29.03.2023, the firm presented the proposal for grant of permission to conduct Phase III clinical trial after revising the study protocol w.r.t. three observations before the committee. After detailed deliberation, the committee recommended that firm should provide scientific justification for use of glucocorticosteroids w.r.t point no. 2 of earlier recommendation for taking further

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			action on the proposed Phase III trial.
16.	CT/25/23 Online Submission (36553) Camizestrant	M/s. Labcorp	The proposal was deferred for next SEC meeting.
17.	CT/97/22 Online Submission (33424) Pertuzumab & Trastuzumab	M/s. Roche	In light of earlier SEC recommendations dated 28.03.2023 & 29.03.2023, the firm presented the proposal for grant of permission to conduct Phase IIIb clinical trial vide protocol no. MO43110, version 1.0 dated 02-Feb-2022 before the committee. After detailed deliberation, the committee recommended for the grant of permission to conduct the proposed Phase IIIb clinical trial based on justifications as presented by the firm.
18.	CT/70/21 Online Submission (23341) Polatuzumab Vedotin	M/s. Roche	The proposal was deferred for next SEC meeting.