

Recommendations of the SEC (Oncology & Haematology) made in its 146th meeting held on 11.04.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/23/000004 Ferumoxytol Injection 510 mg	M/s. MSN Laboratories Pvt. Ltd.	<p>The firm presented their proposal for manufacturing and marketing of Ferumoxytol Injection 510mg elemental Iron/17mL (30mg/ml) along with the request of Phase III clinical trial waiver & bioequivalence study waiver before the committee.</p> <p>After detailed deliberation, the committee recommended that the firm should conduct preclinical studies, Phase III study in India & present the published pharmacokinetics data before the committee.</p> <p>Accordingly, the firm should submit the preclinical studies, Phase III study protocol and published pharmacokinetics data to CDSCO for further consideration.</p>
2.	12-01/23-DC (Pt-56) Ibrutinib 140mg capsules	M/s. Johnson & Johnson	<p>The firm presented its proposal for update of Package Insert (PI) revision based on Company Core Data Sheet dated 24-May - 2021, 06-Nov-2021 and 12-May-2022.</p> <p>After detailed deliberation, the committee recommended for grant of approval for the proposed updation in prescribing information in its presented form.</p>
3.	ND/IMP/20/000031 Lorlatinib Tablets 25mg/100mg	M/s Pfizer Product India Pvt. Ltd.	<p>In light of earlier SEC recommendation dated 28.03.2019, the firm presented the Phase IV clinical trial report before the committee.</p> <p>The permission for import and marketing of Lorlatinib Tablets 25mg and 100mg was already granted on 26.12.2019 with condition to conduct the Phase IV clinical trial and permission to conduct Phase IV clinical trial was already issued to the firm on 02.07.2020.</p> <p>After detailed deliberation, the committee considered the result of Phase IV clinical trial report.</p>

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Biological Division			
4.	4-76/NovoNordisk/PAC-R-Catridecacog/2021-BD Catridecacog (recombinant coagulation factor XIII) 2500 IU Lyophilized powder for conc. for solution for Injection	M/s. Novo Nordisk India Pvt. Ltd.	The proposal is deferred for next meeting.
SND Division			
5.	SND/IMP/22/000042 Ruxolitinib tablets 5mg, 10mg, 15mg, 20mg	M/s. Novartis Healthcare	The proposal is deferred for next meeting.
6.	SND/MA/23/000061 Methotrexate oral solution 2mg/ml	M/s. Beta Drugs Ltd.	The proposal is deferred for next meeting.
GCT Division			
7.	CT/117/21 Online Submission (22130) Datopotamab	M/s. AstraZeneca	The firm presented proposal of protocol amendment no. 3 (version no. 4.0) dated 10-Oct-2022 of study protocol no. D92608C0001 before the committee. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
8.	CT/110/21 Online Submission (20852) Oral asciminib	M/s. Novartis	The firm presented proposal of protocol amendment version no. 1 dated 09-May-2022 of study protocol no. CABL001J12301 before the committee. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
9.	CT/17/21 Online Submission (22781) Ruxolitinib	M/s. Novartis	The firm presented proposal of protocol amendment version no. 4 dated 04-March-2022 of study protocol no. CINC424A2X01B before the committee. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
10.	CT/100/22 Online Submission (33813) JDQ443	M/s. Novartis	The firm has presented the phase II clinical trial protocol no CJDQ443B12201, version 00 dated 08-06-2022 before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the proposed phase II study with following conditions-

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			<p>1. The applicant should submit clinical study report of Phase Ib/II study to CDSCO.</p> <p>2. PI and Sponsor should report all death irrespective of its cause i.e. PD as SAE till the completion of trial to CDSCO as per provision of NDCT Rules 2019.</p>
11.	<p>CT/89/21 Online Submission (26688)</p> <p>Lutetium (177Lu) Edotreotide</p>	Ms. PSI CRO	<p>The firm has presented protocol amendment version 3.0 dated 22-07-2022 to protocol no. DP1111-02CT before the committee.</p> <p>After detailed deliberation, the committee recommended for approval of proposed protocol with following conditions-</p> <p>1. The sub study i.e. genomic profiling should not be part of the parent protocol and India subject should be excluded from the study which is optional for future research/genomic profiling.</p> <p>2. PI and Sponsor should report all death irrespective of its cause i.e. PD as SAE till the completion of trial to CDSCO as per provision of NDCTR 2019.</p>
12.	<p>CT/47/20 Online Submission (22750)</p> <p>Durvalumab</p>	M/s. AstraZeneca	<p>The firm presented proposal of protocol amendment version no. 4.0 dated 02-Aug-2022 of study protocol no. D910LC00001 before the committee.</p> <p>After detailed deliberation, the committee recommended the approval of the protocol amendment as presented by the firm.</p>
13.	<p>CT/95/19 Online Submission (18331)</p> <p>Selpercatinib</p>	M/s. Eli Lilly	The firm did not turn up for presentation.
14.	<p>CT/44/21 Online Submission (23581)</p> <p>Atezolizumab</p>	M/s. Roche	The firm did not turn up for presentation.
15.	<p>CT/151/22 Online Submission (34938)</p> <p>KRC-01</p>	M/s. Prorelix Services	In light of earlier recommendation of SEC meeting held on dated on dated 28.03.2023 & 29.03.2023 wherein it was recommended that the proposal will be deliberated in presence of Radio-oncologist. The firm presented their phase 1/2 clinical trial protocol number: KRC-01-C01, Original protocol version 1.0 Nov

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			<p>02, 2022 in presence of Radiation Oncologist before the committee.</p> <p>After detailed deliberation the committee recommended that the applicant should submit the following for further review by the committee-</p> <ol style="list-style-type: none"> 1. No of subjects (60) proposed in phase II part of the trial should be statistically justified. 2. Rationale for proposing 10 subjects in phase I study from India only even the safety is not well known of study drug. 3. Subject only with FIGO stage III locally advanced cervical cancer should be enrolled in phase I part of the study. 4. Justification for dose volume of study drug as $\leq 40\text{cc}$ and $\geq 140\text{cc}$ of tumor size. 5. Submission letter/ approval letter from other participating countries.
16.	<p>CT/04/23 Online Submission (35658)</p> <p>HT-6184</p>	M/s. CBCC	The proposal is deferred for next meeting.
17.	<p>CT/38/21 Online Submission (21991)</p> <p>JNJ-42756493</p>	M/s. J&J	<p>The firm has presented protocol amendment 9 dated 04-10-2022 to clinical trial protocol no 42756493BLC2001 before the committee.</p> <p>After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.</p> <p>Note- Dr. C. K. Bose did not participate in deliberation.</p>
18.	<p>CT/38/21 Online Submission (21237)</p> <p>Amivantamab+ Lazertinib</p>	M/s. J&J	<p>The firm has presented protocol amendment 3 dated 22-08-2022 to clinical trial protocol no 73841937NSC3003 before the committee.</p> <p>After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.</p>