

Recommendations of the SEC (Oncology & Haematology) made in its 135th meeting held on 19.10.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	NA/MA/22/000084 Apalutamide 60 mg Tablets	M/s. BDR Pharmaceuticals International Pvt. Ltd.	In light of SEC recommendation dated 15.06.2022, the firm presented their proposal for manufacture and market of Apalutamide 60 mg tablets along with result of BE study before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the drug for the proposed indication subject to condition that the firm should conduct a Phase IV clinical trial for which protocol should be submitted within 3 months of approval of the drug for review by the committee. The drug should be sold by retail under the prescription of the Oncologist or Urologist only.
2.	ND/IMP/21/000040 Pralsetinib Capsules 100 mg	M/s. Roche	The firm did not turn up for presentation.
Biological Division			
3.	BIO/CT/22/000089 Pertuzumab 420mg/14mL (30 mg/mL)	M/s. Intas Pharmaceuticals Ltd.	The firm presented the protocol for conduct of study titled “A randomized, double-blind, three-arm, balanced, single-dose, Phase I, parallel-group study comparing pharmacokinetics of Pertuzumab (420 mg solution for Infusion) of Intas Pharmaceuticals Limited, India with Perjeta® of Genentech Inc, a member of Roche Group, USA and Perjeta of Roche Pharma AG, Germany in normal, healthy, adult human male subjects” Protocol No.: 0130-21; Version No. 1.0; Dated:20 July 2021. After detailed deliberation, the committee recommended for approval for conduct of the study with the condition that the Study title should be revised removing the word “Phase I” as per present objective of the study.

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			<p>Further, the firm should submit detailed information and literature references on volume of distribution profile of the innovator's drug as discussed during the presentation.</p> <p>Accordingly, the revised protocol should be submitted to CDSCO for review.</p>
SND Division			
4.	SND/MA/22/000217 Lenvatinib Capsule 12/18/24 mg	M/s. Shilpa Medicare	<p>The firm presented the BE study report of Lenvatinib Capsule 24 mg before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacturing and marketing of Lenvatanib Capsule 12 mg,18mg and 24 mg.</p>
GCT Division			
5.	CT/166/21 Online Submission (17071) Acalabrutinib	M/s. Labcorp	<p>The applicant has presented protocol amendment version 3.0 dated 05-10-2021 before the committee.</p> <p>After detailed deliberation, the committee recommended for approval of proposed protocol amendment.</p> <p>The committee noted that there is no Govt site proposed for the presented clinical trial and hence it is suggested to include Govt site(s) in the trial.</p>
6.	CT/53/22 Online Submission (32595) Lazertinib/Amivantamab	M/s. J&J	<p>The firm has presented Phase III clinical trial protocol no. 61186372NSC3004 (PALOMA 3) before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the study with following conditions-</p> <ol style="list-style-type: none"> 1.The study should be conducted initially in 25 subjects from India and applicant should submit their data for review by the committee for further continuation of the trial. 2. Death irrespective of its cause i.e. PD should be considered as SAE and same to be reported to the CDSCO as per provisions of the New Drugs and Clinical Trial Rules, 2019 during the trial.

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			Accordingly, firm should submit protocol addendum for the same to CDSCO.
7.	CT/81/22 Online Submission (33473) Lorlatinib	M/s. Pfizer	The applicant presented Phase IV clinical trial protocol no B7461027 dated 22/01/2020 before the committee. After detailed deliberation, the committee opined that the applicant should present the protocol with proper justification as there is no unmet need in the country, and the drug is already approved for same indication as proposed in protocol.
8.	CT/83/22 Online Submission (33472) BCD-201	M/s. IR Innovate	The firm presented the proposed study protocol no. BCD-201-2, Version 2.0 (Amendment 1) dated 14JUL2022 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed study with the following conditions: 1.The firm should submit the Interim Study Report no. 1 of approx. 89 subjects for review of the SEC/CDSCO and further continuation of the trial in the country. 2. Death irrespective of its cause i.e. PD should be considered as SAE and same to be reported to the CDSCO as per provisions of the New Drugs and Clinical Trial Rules, 2019 during the trial. Accordingly, firm should submit protocol addendum for the same to CDSCO.
9.	CT/79/22 Online Submission (33423) BCD-217	M/s. IR Innovate	In light of earlier SEC held on 27/09/2022 the applicant presented justification along with interim report of Phase II study before the committee. After detailed deliberation, the committee reiterated its earlier recommendation and recommended for grant of permission to conduct the proposed study with the condition that death irrespective of its cause i.e. PD should be considered as SAE and same to be reported to the CDSCO as per provisions of the New Drugs and Clinical Trial Rules, 2019 during the trial. Accordingly, the firm should submit

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