

Recommendations of the SEC (Investigational New Drugs) made in its 01st/24 meeting held on 30.01.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
IND Division			
1.	IND/MA/19/000009 Remogliflozinatabonate and Remogliflozinatabonate + Metformin hydrochloride Fixed Dose Combination Tablets	M/s. Glenmark Pharmaceuticals Limited	The firm presented their clinical study report of active PMS before the committee. After detailed deliberation, the committee recommended that the firm should present the comprehensive data on all outcome measures of safety and efficacy as per the already approved protocol including PSUR data for further review by the committee.
2.	IND/CT/23/000083 Nor-Ursodeoxycholic acid tablets 500 mg	M/s. Shilpa Medicare Limited	The firm presented their proposal of Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended that the firm should perform the trial preferably with Hepatologist and needs to have fair participation of Government Centers also. The study protocol shall include clinical outcome measures as primary efficacy end point along with other suitable markers. Therefore the firm should submit revised protocol to CDSCO for further review by the committee.
3.	IND/CT/23/000051 Anti-PCSK9 Product (ZRC-3306) (Re-Deliberation)	M/s. Zydus Life Sciences Limited	The firm has requested for removal of condition mentioned in Phase 1 Clinical Trial permission issued in Form CT-06 granted vide permission No. CT/ND/(IND)/36/2023 dated 19.09.2023 i.e. "After completion of the first dose cohort, the report should be presented before the committee for proceeding to the next dose cohorts". Firm has presented their justification for removal of the above condition before the committee. After detailed deliberation, the committee recommended that the trial may proceed to dose the 2 nd and 3 rd Cohorts under the DSMB Monitoring.
4.	IND/MA/19/000036 Endoxifen Tablets 8mg	M/s. Intas Pharmaceuticals Limited	The firm presented the study report of Phase IV of Endoxifen Tablets 8 mg before the committee. After detailed deliberation, the committee noted the results of the Phase IV study presented by the firm and recommended to include the safety data generated from the trial, in the prescribing information. Accordingly, the firm should

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			present prescribing information to CDSCO for review by the committee.
5.	IND/CT/23/000030 Orthosiphon Stamineus Effervescent Powder	M/s. Synergen Bio Private Limited	The firm presented their proposal for reconsideration of Phase I clinical trial protocol before the committee. After detailed deliberation, the committee opined that the firm should provide justification of 4 doses per day when $t_{1/2}$ is 8hrs. The committee further noted that the proposed study design is not sufficient to establish PK and ADME profile. Further the firm has not submitted data as per Table 4 of Second Schedule in New Drugs and Clinical Trial Rules, 2019. Therefore the request of the firm for reconsideration of proposal to conduct Phase I cannot be considered for approval and may be rejected.
6.	IND/CT/23/000092 JBI-778 (as freebase) 20.00 mg, 100.00 mg, 250.00 mg.	M/s. Jubilant Therapeutics India Limited	The firm presented their proposal of Phase 1 clinical trial protocol before the committee. After detailed deliberation, the committee recommended to conduct the Phase 1 Clinical trial as per the protocol submitted in its presented form.
7.	IND/CT/23/000101 Halofuginone Hydrobromide Oral Gel 0.01, 0.03 and 0.06% w/w	Yenepoya Foundation For Technology Incubation , C/o Yenepoya University	The proposal was deferred to next SEC meeting.
8.	IND/CT/23/000093 BSG005 Lyophilized powder for solution for Intravenous	M/s. Alkem Laboratories Ltd.	The firm presented their proposal of Phase 1b clinical trial protocol before the committee. After detailed deliberation, the committee permitted to conduct the study in tertiary care centres with ICU and emergency care management with medical intensivist as PI and Co-Investigators from microbiology and Radiology.