

Recommendations of the SEC meeting to examine IND proposals, made in its 38th meeting held on 25.08.2023, 12:00 Noon at CDSCO (HQ), New Delhi, through Webex (Video Conference):

Sr.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Investigational New Drugs Division			
1.	F. No. IND/CT/22/000003 SN-38 lipid suspension	M/s. Intas Pharmaceuticals Limited	The firm presented the data of the 1 st dose cohort and requested permission to proceed for the next dose cohort of the approved Phase I clinical trial protocol no. 0451-21 version 1.2 dated 07.05.2022. After detailed deliberation, the committee recommended to proceed for the next dose levels as per the approved Protocol.
2.	F. No. IND/CT/23/000057 SCD-153 topical solution	M/s. Sun Pharma Advanced Research Company	The firm presented their proposal to conduct Phase I clinical trial protocol no. SCD-153-22-01. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I study as per the protocol presented subject to the following condition: The safety data of the first two dose cohorts should be presented before the committee for proceeding to the next dose.
3.	F. No. IND/CT/23/000051 Anti-PCSK9 product (ZRC-3306)	M/s. Zydus Life sciences Limited	The firm presented their proposal to conduct Phase I clinical trial protocol no. ZYPCSK9 1001; Ver. No. 1.0 dated 29 th May 2023 along with the justification regarding pre clinical data in higher animal species. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I clinical trial as per the protocol presented by the firm subject to the following conditions: 1. After completion of the first dose cohort, the report should be presented before the committee for proceeding to the next dose cohorts. 2. Based on the presented justification the firm should present the interim report on repeated dose toxicity studies in the higher animal species proposed to the committee. 3. The DSMB shall include Cardiologist, Pharmacologist and Internal Medicine expert.