

Recommendations of the SEC (Investigational New Drugs) made in its 03rd/24 meeting held on 22.03.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
IND Division			
1.	IND/CT/24/000016 ZYAT1 Tablets 50mg and 250mg	M/s. Zydus Lifesciences Limited	The firm presented their proposal to conduct Phase I clinical trial before the committee. After detailed deliberation, the committee recommended the following: 1. The firm should revise the protocol to open label study with pharmacokinetic and exploratory pharmacodynamics as primary outcome measures instead of double-blind, placebo-controlled study. 2. The firm should also include Estimation of plasma Lysophosphatidic acid (LPA) as co-primary objective. 3. The firm should include 8 participants on the trial drug in each cohort. Accordingly, the firm should submit the revised protocol to CDSCO for further review by the committee.
2.	IND/CT/24/000006 LNP8701 Tablets 10 mg, 50 mg	M/s. Lupin Limited	The firm presented the revised protocol number LRP/LNP8701/2023/003 version 1.1 dated 04.03.2024 for conduct of Phase-I clinical trial with LNP8701. After detailed deliberation, the committee recommended the conduct of the trial in its presented form.
3.	IND/CT/24/000012 ZY-19489 Capsules 300 mg	M/s. Zydus Lifesciences Limited	The firm presented their proposal to conduct Phase III clinical trial with ZY19489. After detailed deliberation, the committee recommended as follows that the firm should conduct Phase II study with the drug in P. vivax malaria patients and Phase III study in P.falciparum patients and accordingly the sample size should be recalculated with 90% power. The revised protocol should be submitted to CDSCO for further review by the committee.