Recommendations of the SEC (Investigational New Drugs) made in its 10th/26 meeting held on 27.05.2026 at CDSCO (HQ), New Delhi:

S. No.	File Number, name of drug, strength and dosage form	Name of firm	Recommendations
IND Division			
1.	IND/CT04/FF/2026/56673 Usnoflast (ZYIL1) 75mg (Usnoflast (ZYIL1) 50 mg capsule + Usnoflast (ZYIL1) 25 mg capsule)	M/s. Zydus Lifesciences Limited	Firm has presented Phase-I clinical trial protocol titled "An Open-Label, Phase-1 Study to Evaluate the Pharmacokinetics, Safety, and Tolerability of Usnoflast 75 mg Single dose in Participants with Mild, Moderate, Severe Renal Impairment and healthy volunteers" vide Protocol Number: USNO 1001 version No. 02 dated 19.03.2026 before the committee. After detailed deliberation, the committee recommended to conduct Phase-I clinical trial with following conditions: 1. Firm should exclude subjects having albuminuria < 1000 mg/day. 2. The body weight criteria for matching healthy subject should be ±15% instead of ±15 kg body weight. Accordingly, firm should submit the revised protocol to CDSCO.
2.	IND/CT04/FF/2026/56737 Usnoflast (ZYIL1) 75mg (Usnoflast (ZYIL1) 50 mg capsule + Usnoflast (ZYIL1) 25 mg capsule	M/s. Zydus Lifesciences Limited	Firm has presented Phase-I clinical trial protocol titled "A Phase I, Open-label study to evaluate the pharmacokinetics, safety and tolerability of Usnoflast 75mg single dose in participants with Normal function and participants with Hepatic Impairment" vide Protocol Number: USNO 1002version No. 02 dated 19.03.2026 before the committee. After detailed deliberation, the committee recommended toconduct Phase-I clinical trial with following conditions: 1. Child"C" Hepatic impairment patient should be excluded from the study. 2. The clinical sites should have a Hepatology division with an ICU facility and a hepatologist should be a part of the team of investigators. Accordingly, firm should submit the revised protocol to CDSCO.