

Recommendations of the SEC (Investigational New Drugs (IND) made in its 06th/25 meeting held on 08.07.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
IND Division			
1.	IND/CT04/FF/2024/4 6992 AUR 103 Calcium 100 mg Capsules	M/s. Aurigene Oncology Ltd.	<p>Firm has presented proposal to conduct Phase II trial entitled “A Phase II Study Evaluating the Efficacy and Safety of AUR103 Calcium in Patients with Advanced, Well or Moderately differentiated Neuroendocrine Tumours (Bharat- 3)” vide Protocol no. AUR103-202, Version 2.0, Date 04.07.2025 (Proof of concept study).</p> <p>After detailed deliberation, the committee has observed that firm has not completed Phase I/IIa study and the results shown are inadequate with respect to safety of drug.</p> <p>Committee has recommended for submission of complete CSR of Phase I/IIa (Part 1, Part 2A, Part 2B) study as and when completed to CDSCO based on which the Phase II study protocol will be considered for further deliberation in the SEC.</p> <p>Accordingly, firm is required to submit the complete CSR of Phase I/IIa study as and when completed along with proposed Phase II clinical study Protocol (AUR103-202, version 2.0) to CDSCO for further deliberation in SEC.</p>
2.	IND/CT04/FF/2025/4 9408 Nafithromycin 400 mg tablet.	M/s Wockhardt Limited	Under Discussion.
3.	IND/CT/25/000026 Usnoflast (ZYIL 1) 75 mg, 50 mg & 25 mg.	M/s. Zydus Lifesciences Limited	Firm has presented drug-drug interaction phase I protocol titled “A drug-drug interaction study of Treatment A [Usnoflast (ZYIL1) 75mg (Usnoflast (ZYIL1) 50 mg capsule + Usnoflast (ZYIL1) 25 mg capsule)] and Treatment

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			<p>B [Caffeine Citrate Oral Solution, USP 20 mg/mL, (equivalent to 10 mg/mL of caffeine base) (Dose = 100 mg of Caffeine base), Midazolam Hydrochloride syrup 2mg/mL (Each mL contains 2 mg of Midazolam base) (Dose = 2 mg) and Bupropion 75mg Tablet] in healthy adult human subjects under fasting conditions” vide Protocol No.: C1B05514, Version 01 dated: 12.03.2025</p> <p>After detailed deliberation the committee recommended to complete ongoing Phase II study & submit Clinical study Report, based on the safety reports committee will further take decision on present protocol.</p> <p>Accordingly, firm should submit Phase II CSR as and when completed along with above mentioned proposed drug-drug interaction Phase I clinical study Protocol (No.: C1B05514, Version 01 dated: 12.03.2025) for further deliberation and review by the committee.</p>