

**Recommendations of the SEC (Investigational New Drugs) made in its 9<sup>th</sup>/26 meeting held on 20.05.2026 at CDSCO (HQ), New Delhi:**

S. No.	File Number, name of drug, strength and dosage form	Name of firm	Recommendations
<b>IND Division</b>			
1.	IND-12013(19)/1/2026-e-office  AUR 108,10 mg & 50 mg capsules	M/s. Aurigene Oncology Limited	<p>Firm had been issued Phase-I clinical trial permission under Form CT-06 titled as "A Phase 1, Open Label, Dose Escalation, Dose Expansion, Multicenter Study Evaluating the Safety, and Pharmacokinetics Pharmacodynamics of Oral AUR108 in Patients with Relapsed Advanced Lymphomas (ASHA-1) vide Protocol No. AUR 108-101 version 1.0 dated 13.03.2023."</p> <p>Further, firm has amended study protocol (AUR108-101 version 4.0 dated 13.03.2023) to include Chronic Lymphocytic Leukaemia (CLL) patient and same were deliberated in 03<sup>rd</sup>/25 SEC meeting on 30.04.2025. After detailed deliberation on data presented by firm with respect to in-vitro cell line study and other data, the committee agreed and recommended to include patient with Chronic Lymphocytic Leukaemia (CLL). The firm should outline the SAE's separately for each indication and present while presenting CSR of the study which is currently ongoing.</p> <p>The firm presented amendment in Phase-I clinical study protocol (AUR) 108-101 version 5.0 dated 06.03.2026; due to incorporation of fresh biopsy collection for predictive biomarker evaluation.</p> <p>After detailed deliberation, the committee noted amendment made in protocol and recommended to conduct the study as per amended protocol presented by the firm.</p>

S. No.	File Number, name of drug, strength and dosage form	Name of firm	Recommendations
2.	IND/CT04/FF/2026/54359  Nilotinib Hydrochloride Monohydrate Tablet 150 mg, Varespladib Methyl Tablet 200 mg, Marimastat Tablet 250 mg	M/s Vhypotenuse Pvt. Ltd.	<p>The firm has applied for grant of permission to conduct a Phase I Clinical Trial vide protocol no.DYC2601/UADH/001 Version 1.0 dated 19.01.2026.</p> <p>In light of earlier SEC recommendation dated 25.03.2026, firm presented Non-clinical data and Phase - I study protocol.</p> <p>After detailed deliberation, the committee recommended to conduct Phase I Clinical Trial with following conditions: -</p> <ol style="list-style-type: none"> <li>1. During administration of IMP subject shall be admitted at Phase-I clinical trial site for the duration of the study.</li> <li>2. Inclusion of trough concentration sampling at 3, 4 and 5 days in MAD study.</li> <li>3. If there is any abnormality reported in ECG, subject shall be placed on Holter.</li> <li>4. PK sampling time points may be reviewed based on knowledge of constituent drug of the applied IMP product.</li> </ol> <p>Accordingly, firm should submit revised protocol to CDSCO for further review.</p>