

Recommendations of the SEC (Investigational New Drugs) made in its 14th/26 meeting held on 16.07.2026 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/2019/17916 CA-170 Capsules 100 mg	M/s. Aurigene Oncology Limited	The firm presented the proposal for discontinuation of Phase-IIb/III clinical trial before the committee. After detailed deliberation, the committee agreed for the discontinuation of the study.
2.	IND/CT04/FF/2026/56869 AUR 114 Injection (100 mg/vial)	M/s. Aurigene Oncology Limited	Firm presented the non-clinical study data and Phase I clinical trial study protocol (Protocol No. AUR 114-101 version 2.0 dated 23.04.2026) before the committee. After detailed deliberation, the committee recommended that: - 1) Intra cohort dose escalation (Part-I) should be included in study design to allow lower dose level patient to move to next higher dose subject to tolerability and higher efficacy being seen in higher dose. 2) Result of Part - I study should be submitted to CDSCO for deliberation by the committee before proceeding to Part- II study. Accordingly, firm should submit the revised protocol to CDSCO for approval.