

Recommendations of the SEC (Investigational New Drugs) made in its 05th/26 meeting held on 25.03.2026 at CDSCO (HQ), New Delhi:

S.No	File Number, Name of Drug, Strength and dosage form	Firm Name	Recommendations
IND Division			
1.	IND/CT04/2026/54257 ZY-19489 900mg tablet	M/s. Zydus Lifesciences Limited	<p>Firm presented Phase-II Clinical Study Report and Phase-III Clinical Trial Protocol.</p> <p>After detailed deliberation, committee noted the results of Phase-II Clinical Study and recommended to conduct Phase-III Clinical trial as per protocol presented by the firm with following amendment in study protocol:</p> <p>1) Firm should include Rapid diagnostic test to differentiate between P. falciparum & P. vivax strain before patient enrolment to the study.</p> <p>Accordingly, firm should submit the revised protocol to CDSCO for further review.</p>
2.	IND-12013(19)/3/2025-eoffice LNP3693, Solution for Injection 2mg/ml	M/s. Lupin Limited	<p>Firm presented amended Phase-I Protocol no. LRP/LNP3693/2023/001 version 4.0 dated 20.02.2026 before the committee in continuation to the earlier 2nd/26 SEC (IND) meeting held on 05.02.2026.</p> <p>After detailed deliberation, the committee noted amendments made to the protocol and recommended for conduct of the study as per amended protocol presented by the firm.</p>
3.	IND/CT04/FF/2026/54359 Nilotinib Hydrochloride Monohydrate Tablet 150 mg Varespladib Methyl Tablet 200 mg, Marimastat Tablet 250 mg	M/s. Vhypotenuse Private Limited	<p>Firm presented the Non-clinical data before the committee.</p> <p>After detailed deliberation, committee recommended the following:</p> <p>1) Firm should submit complete Non-Clinical Data as per NDCT rules 2019, as and when completed.</p> <p>2) Firm should submit Clinical Trial Data generated, if any, in</p>

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			other countries/ in country for the proposed Combikit. Accordingly, firm should submit above mentioned data for further evaluation by the committee.
4.	IND/CT04/FF/2025/52715 AUR103(Bharat-4)	M/s. Aurigene Oncology Limited	The firm did not attend the meeting
5.	IND-12013(17)/1/2026-eoffice AUR 103 Calcium (Bharat-2)	M/s. Aurigene Oncology Limited	The firm did not attend the meeting
6.	E-134639 AUR104	M/s. Aurigene Oncology Limited	The firm did not attend the meeting
7.	E-137832 AUR106	M/s. Aurigene Oncology Limited	The firm did not attend the meeting