

Recommendations of the SEC (Investigational New Drugs (IND)) made in its 03rd/25 meeting held on 30.04.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
IND Division			
1.	IND/CT/23/000021 AUR-108	M/s Aurigene Oncology Limited	<p>In response to previous SEC meeting recommendations, dated 28.02.2025, firm has presented the data i.e. in-vitro cell line study etc. for Phase I study Protocol AUR 108-101, version 4.0 dated 27.03.2025 to SEC for approval to include Chronic Lymphocytic Leukemia (CLL) patients in the study.</p> <p>After detailed deliberation, the committee agreed and recommended to include patients with Chronic Lymphocytic Leukemia (CLL) and in subsequent presentations outline the SAEs separately for each indication.</p>
2.	IND/CT04/FF/2025/4 8187 ZYIL1	M/s Zydus Lifesciences	<p>Firm has presented the protocol to conduct “Single dose oral food effect bioavailability study of Usnoflast (ZYIL1) 75mg (Usnoflast (ZYIL1) 50 mg capsule + Usnoflast (ZYIL1) 25 mg capsule) in healthy adult human subjects under fasting and fed conditions” before the committee.</p> <p>After detailed deliberation, the committee did not agreed and recommended to submit first the result of Phase II studies to CDSCO for further review by committee.</p> <p>Therefore, once the safety has been established firm may present requisite data to conduct the said study.</p>
3.	IND/CT04/FF/2025/4 7843 ZYIL1	M/s Zydus Lifesciences	<p>Firm has presented the CSR of Phase II a (proof of concept) study and protocol to conduct “A randomized, double blind, parallel, placebo-controlled, interventional phase II trial to evaluate the efficacy and safety of Usnoflast for the treatment of participants with mild to moderately active Ulcerative Colitis not responding to or intolerant to oral aminosalicylates” before the committee.</p> <p>After detailed deliberation, the committee has noted the result of Phase IIa study</p>

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			and recommended for grant of permission to conduct the Phase II trial as per the protocol as presented by the firm.
4.	IND-11012(17)/2/2025-eoffice Nafithromycin Tablet 400mg	M/s. Wockhard Ltd.	<p>Firm has presented the proposal to remove the condition “For supply only to Medical college/ Tertiary Care Hospital/ District Hospital” from the label of drug Nafithromycin Tablet 400 mg, before the committee.</p> <p>After detailed deliberation, the committee has opined that firm has not presented robust plan to ensure drugs inappropriate use to combat AMR.</p> <p>Moreover, firm has not yet conducted Phase IV trial and therefore the effectiveness of product has not been established in real world.</p> <p>Hence committee did not agree for removal of stipulated condition.</p> <p>Firm may come up with robust plan and patient distribution data for further deliberation.</p>