

**Recommendations of the SEC (Investigational New Drugs) made in its 09<sup>th</sup> /25 meeting held on 08.10.2025 at CDSCO (HQ), New Delhi:**

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>IND Division</b>			
1.	IND-11012(17)/2/2025-eoffice  Nafithromycin 400 mg Tablet (Removal of condition)	M/s. Wockhardt Ltd	Under discussion.
2.	IND/CT04/FF/2025/49677  Nafithromycin 400 mg Tablet	M/s. Wockhardt Ltd	In light of earlier SEC recommendation dated 04.09.2025, firm has presented the revised phase III Protocol No. W-4873-302, version no. 2.0 dated 15 Sep 2025, before the committee.  After detailed deliberation, the committee recommended for approval of revised Phase III study protocol as presented by the firm with condition that treatment should be started within 24 hours after confirmation of Acute Bacterial Rhinosinusitis (ABRS).  Accordingly, firm should submit revised protocol to CDSCO for further action.
3.	IND/CT04/FF/2025/48187  Usnoflast (ZYIL1)	M/s Zydus Lifesciences Limited	In light of earlier SEC recommendation dated 30.04.2025, the firm informed that the safety data of Phase II studies was presented before the committee, on 04.09.2025.  Firm presented study protocols for conduct of single dose oral food effect bioavailability study in healthy adult subjects under fasting and fed conditions.  After detailed deliberation, the committee made note of the safety data presented and considered for approval of study protocol no. C1B05513, version no. 02 dated 05 March 2025 as presented by firm.
4.	IND/CT04/FF/2025/51305  Utreglutide (GL0034) Solution for injection	M/s. Sun Pharmaceuticals Industries Limited.	The firm presented pre-clinical study, result of Phase I clinical trial conducted in Belgium and Phase II Clinical Trial Protocol No. ICR/25/014 Version 1.0 for the indication Type II diabetes mellitus (T2DM) with request for waiver of local Phase I clinical study, before the committee.  After detailed deliberation, the committee

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			<p>noted the justification for waiver of local Phase I clinical study with following changes in the Phase II study protocol; -</p> <ol style="list-style-type: none"> <li>(1) Study title should be revised to include overweight and obese patients, as the subject with BMI 23-45 kg/m<sup>2</sup> (both inclusive) are planned to be included in the study.</li> <li>(2) Study protocol w.r.t. inclusion and exclusion criteria should be revised in-line with that of the planned Global clinical trial study.</li> <li>(3) Adverse events i.e., Nonarteric Anterior Ischemic Optic Neuropathy, Kidney injury, alopecia etc, observed with other GLP-1 receptor agonist drugs should also be monitored in proposed Phase II clinical study for Utreglutide (GL0034) Solution for injection.</li> </ol> <p>Accordingly, firm should submit revised protocol to CDSCO for further evaluation by the SEC.</p>