Recommendations of the SEC meeting to examine IND proposals, made in its 25th meeting held on 02.08.2022, 12:00 PM at CDSCO, HQ New Delhi, through Webex (Video Conference):

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
1 & 2	**F. No IND/CT/22/000055 & F. No. IND/CT/21/000025 ZY-19489**	**M/s Zydus Life Sciences Ltd.,**	The firm presented Phase I clinical trial report alongwith their proposal to conduct Phase II Clinical Trial protocol before the committee. After detailed deliberation, the committee noted the phase I clinical trial report and recommended for grant of permission to conduct the Phase II Clinical trial as per the presented protocol with the condition that the study should be a observer blind study. Accordingly, the firm should submit revised protocol to CDSCO.
3.	**F. No. IND/CT/22/000008 (+)- -DHTBZ**	**M/s Synapse Labs Pvt. Ltd.,**	The firm presented their proposal to conduct Phase-I clinical trial protocol alongwith preclinical data before the committee. After detailed deliberation, the committee recommended that the firm should submit the following for further deliberation in the committee. 1. Details of dosage form and strength to be used in the proposed study. 2. Justification for the proposed Human dose extrapolated from No Observed Adverse Effect Level (NOAEL), Low Observed Adverse Effect Level (LOAEL) and Maximum Tolerated Dose (MTD).
4.	**F. No. ND/CT/20/000101 Levonadifloxacin Tablets**	**M/s Wockhardt Limited**	The firm presented the Phase IV protocol amendment before the committee for non-exclusion of smokers and alcoholic patients from the study. After detailed deliberation, the committee recommended for grant of approval for the amendment in Phase IV clinical trial protocol vide Clinical Study Protocol WOC/LEV/CT-11/19 Version 2.0 dated 23.03.2021.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
5.	**F. No. ND/CT/22/000021** **PNB-001**	**M/s Biosphere Clinical Research Pvt. Ltd**	The firm presented their proposal to conduct Phase II clinical trial alongwith preclinical & clinical data before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the presented protocol.
6.	**F. No. IND/MA/21/000010** **2DG (2-Deoxy-D-Glucose)**	**Dr. Reddy's Laboratories**	The firm did not turn up for meeting.
7.	**F. No. IND/CT/22/000036** **AB001**	**M/s Vopec Pharmaceuticals Private Limited**	The firm presented their proposal to conduct Phase I clinical trial alongwith preclinical data before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the presented protocol with the condition that the starting lower dose should be 40mg/day orally. Accordingly, the firm should submit revised protocol to CDSCO.
8.	**F. No. IND/MA/22/000027** **Sovateltide injection 30µg**	**M/s Pharmazz India Private Limited**	In light of recommendation of the earlier SEC meeting held on 28.06.2022, the firm presented proposalfor permission for manufacturing and marketing along with Phase IV Clinical trial protocol before the committee. After detailed deliberation, the committee recommended grant of permission for manufacturing and marketing and permission to conduct the Phase IV Clinical trial as per the presented protocol subject to the following conditions- 1. Firm should initiate the clinical trial within three months of launching the product in the market. 2. Revised package insert should be submitted to CDSCO for review.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			3. Approval of Revised Package Insert, Label and Carton to be adopted should be obtained from CDSCO before launching the product marketing. 4. The drug should be available on prescription from Specialist only. Three geographically distributed clinical trial sites should be inspected to verify GCP compliance before grant of manufacturing and marketing permission.
9.	**F. No. IND/CT/22/000001** **Sovateltide**	**M/s Pharmazz India Private Limited**	In light of recommendation of the earlier SEC meeting held on 16.02.2022, the firm presented their proposal to conduct Phase II clinical trial protocol alongwith preclinical data before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the presented protocol.