Recommendations of the SEC meeting to examine IND proposals, made in its 39th meeting held on 18.10.2023, 12:00 Noon at CDSCO (HQ), New Delhi, through Webex (Video Conference):

Sr.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Investigational New Drugs Division			
1.	F. No. IND/CT/22/000036 AB001 Tablets (40 mg, 100 mg, 200 mg, 400 mg, 500 mg, 800mg)	M/s Vopec Pharmaceuticals Private Limited	The firm presented the Clinical Study report of the Phase I titled " A phase 1, open label study to evaluate MTD, safety, tolerability and pharmacokinetics of oral drug AB001 in patients with various types of metastatic cancer patients." After detailed deliberation, the committee recommended that the firm should present the Safety data of the study drug in a stratified manner i.e. in patients with metastatic versus locally advanced solid tumor malignancies disease wise; Safety data of patients of lower age group versus higher age group, disease wise. Safety data of study drug in patients considering concomitant drugs for each type of cancer. The firm is also required to present pharmacokinetic data for each of the patients, dose cohort wise . Accordingly, the data should be submitted to CDSCO for further deliberation in the committee.
2.	F.No. IND/CT/21/000004 MSP008-22 200mg Tablets	M/s. Clinexel Life Sciences Pvt.Ltd.	The firm presented the data of the 1st dose cohort (at dose level of 200 mg) along with DSMB report and requested permission to proceed for the next dose cohort of the approved Phase I clinical trial protocol no. No. Clinexel-GBL-002; Version No.: Version 1.1, Date: 18 September 2021. After detailed deliberation, the committee recommended to proceed for the next dose levels as per the approved Protocol.
3.	F.No. IND/CT/21/000030 MSP008-22 200mg Tablets	M/s. Clinexel Life Sciences Pvt.Ltd.	The firm presented the data of two Cohorts (Cohorts 1 and 2 of Single Ascending Dose (at dose levels of 200 mg & 400 mg) along with DSMB report and requested permission to proceed for the next dose cohort of the approved Phase I clinical trial protocol no. Clinexel-GBL-003; Version-01, Date: 28.05.2021. After detailed deliberation, the committee recommended to proceed for the next dose levels as per the approved Protocol.