Recommendations of the SEC (Investigational New Drugs) made in its 10th/24 meeting held on 11.11.2024 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2024/44774 NM8074	M/s Ablenio Sciences Private Limited	The firm presented the proposal for the amendment in the already approved Phase-II study vide Protocol No. NM8074-PNH-103, Version 3.0 dated 10 Nov 2022 for enrolling an additional Cohort (Cohort 3) of PNH patients in the ongoing study. After detailed deliberation, the committee recommended that firm to submit following data for all the patients enrolled in the study as per already approved protocol for further evaluation by the committee - 1. Improvement in hemoglobin level 2. Transfusion requirements 3. LDH levels 4. PNH RBC clone 5. Stabilization of serum Complement C3b (alternative pathway) and Haptoglobin levels. The committee further recommended to submit the justification for the new dose regime in Cohort 3.
IND Division			
2.	IND/CT/24/000031 RP-12146 Tablets 100 mg	M/s. Raptim Research Pvt. Ltd.	As per the recommendations of 06th/24 SEC meeting dated 24.06.2024, the firm presented the revised Phase 1/1b clinical trial protocol vide protocol no. RO12146-2401 ver. 1.1 dated 27.07.2024. After detailed deliberation, the committee noted the changes made in the protocol and recommended to conduct the study with condition that they should perform study with at least 06 subjects at highest dose with inclusion of testing in both serum and urine.
3.	IND-12013(17)/3/2024-eoffice K0706 (vodobatinib)	M/s Sun Pharma Advanced Research Company Limited	The firm presented the interim data of the phase-I clinical trial study along with safety and tolerability PK of K0706. After detailed deliberation, the committee accepted the discontinuation of the study with condition to submit SAE report, if any to the SAE div.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
4.	IND/MA/19/000009 Remogliflozin and Remogliflozin + Metformin Fixed Dose Combination	M/s. Glenmark Pharmaceuticalcals Ltd.	The firm presented the detailed analysis of Serious Adverse Events of Deaths and updated status of the ongoing AE's & SAE's in the active PMS study as per the previous SEC recommendation (05/24th SEC dated 27.05.2024). The committee noted the above data presented by the firm. After detailed deliberation, the committee recommended that the firm should submit the opinion of Sponsor, Principal Investigator & Ethics Committee for observed SAEs of each death case to the CDSCO.
5.	IND/CT/22/000082 AUR 106 Tablets 25 mg & 100 mg	M/s. Aurigene Oncology Ltd.	The firm presented a protocol amendment Protocol No. AUR106-101 version 4.0 Dated 17 Oct 2024 alongwith changes in history. After detailed deliberation, the committee noted the changes made however firm should take approval of SRC before proceeding to 200 mg dose.