Recommendations of the SEC (Investigational New Drugs (IND) made in its 04rd/25 meeting held on 29.05.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
IND Division			
1.	IND/CT04/FF/2024/44989 0.1% Saturated Anacardic Acid Lotion	M/s Avinia Therapeutics Private Limited	The firm has presented in-vitro and in-vivo preclinical data before the committee to conduct the Phase I clinical trial study in indication with Plaque psoriasis. However, the committee has observed that firm has not given adequate justification for not conducting the acute dose toxicity, Dermal toxicity, Photoallergy or Dermal Phototoxicity, Allergenicity/ Hypersensitivity study, pharmacokinetics study, proof of concept study with proposed mechanism of action etc., in animal model. Therefore, after detailed deliberation, the committee has recommended to submit the above mentioned study data in animal model as per NDCT Rules, 2019 along with Phase I clinical protocol to CDSCO for further deliberation in SEC committee.
2.	IND/CT04/FF/2024/46992 AUR103 Calcium	M/s Aurigene Oncology Limited	Firm did not turn up for the presentation.
3.	IND-12011(11)/3/2025- e-office LNP7457	M/s Lupin Ltd	The firm has presented the proposal for expansion of the indications i.e, Head and neck cancer, Breast cancer, Colon cancer instead of Adenoid Cystic Carcinoma (ACC), Glioblastoma Multiforme (GBM), Mantle Cell Lymphoma (MCL) respectively in Part 3 (cohort expansion part) of approved Phase I Clinical trial Protocol version 1.1 dated 31.01.2023 and accordingly presented revised clinical trial protocol entitled " Phase 1 Study to Evaluate Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of LNP7457 in Subjects with Advanced or Metastatic Solid Tumors& Non-Hodgkin's Lymphoma" vide Protocol Number:

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			LRP/LNP7457/2022/002, Date: 30 January 2025, before the committee. After detailed deliberation, the committee recommended for the approval of amendment in Phase I clinical trial protocol as presented by firm with condition to include the risk mitigation plan in protocol. Accordingly, firm needs to submit the revised protocol with risk mitigation plan to CDSCO for further action.
4.	IND/CT04/FF/2025/47801 ZY-19489	M/s Zydus Lifesciences Limited	Firm presented Phase III Clinical study protocol titled "A phase III, multicenter, randomized, assessor-blind, active comparator study to determine the efficacy, safety and tolerability of orally administered ZY-19489 in patients with uncomplicated malaria due to Plasmodium falciparum" vide Protocol No. ZY-19489.23.002 version 04. Firm's Phase III clinical study protocol for ZY19489 for 300 mg capsule dosage formulation (3 x 300mg) was presented in 03rd/24 SEC-IND meeting held on 22.03.2024 and committee had recommended to submit revised protocol with recalculation of sample size with 90% power. Accordingly, firm has presented revised protocol. However, the firm has changed the formulation from capsule to tablet. After detailed deliberation to SEC, the committee observed that firm has not shown adequate data to substantiate Bioavailability of tablet formulation of ZY19489. Therefore, the committee recommended for submission of Bioavailability protocol for proposed tablet formulation of ZY19489 to be deliberated before the committee. Firm's Phase-III protocol will be considered after completion of Bioavailability study and its deliberation in SEC-IND.

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5.	IND/CT/20/000062 AB1001 Gel 1% and 3% w/w	AHAMMUNE BIOSCIENCES PRIVATE LIMITED, India	The firm presented CSR of Phase I clinical trial for AB1001 topical gel along with proposal of Phase II clinical trial protocol entitled "A Phase II, Multicenter, randomized study to evaluate safety and efficacy of topical AB1001 in adult patients with non-segmental vitiligo" vide protocol no. AHA-AB1001-001 Version 1.0 dated 11 Dec 2024. After detailed deliberation the committee noted the results of Phase I trial and agreed for conduct of Phase II study as per presented protocol with condition that any treatment emergent adverse events (TEAEs), toxicity etc., shall be reported to CDSCO with photographic evidences in all subjects.