Recommendations of the SEC (Investigational New Drugs) made in its 12th/26 meeting held on 24.06.2026 at CDSCO (HQ), New Delhi:

S. No.	File Number, name of drug, strength and dosage form	Name of firm	Recommendations
IND Division			
1.	IND/CT04/FF/2026/56482 SPARC121 Topical Foam 1%, 3%	M/s. Sun Pharma Advanced Research Company Limited.	Firm presented the non-clinical study data and Phase Ib clinical trial study protocol before the committee. After detailed deliberation, the committee recommended to conduct Phase-Ib clinical trial as presented by the firm with condition to intimate CDSCO, if there is major dropout of the subjects from the study.
2.	IND-12011(11)/33/2026 e-office IND/CT04/FF/2024/42218 DSePA (3,3' Diselenodipronic acid) 2.5 mg, 5.0 mg, 10 mg.	M/s. Clinexel Life Sciences Private Limited.	Firm presented the non-clinical study data and Phase-I/ II clinical trial study protocol before the committee. After detailed deliberation, the committee recommended following: 1) Toxicological data submitted by the firm is not in line with the proposed study protocol for Multiple Ascending Dose study. 2) The committee recommended that firm should conduct 180 days non-clinical toxicity in GLP accredited laboratory as per the requirements of second schedule of NDCT Rules, 2019 for the Multiple Ascending Dose study. 3) The firm should revise the study protocol from Phase-I/II to Phase-I clinical trial with Single Ascending Dose consisting of one arm with Durvalumab injection considering it as standard of care. 4) The firm shall submit Risk Management Plan for phase-I study. Accordingly, firm should submit available non-clinical study data and revised Phase-I clinical trial protocol for further review by the committee.

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Biological Division			
3.	BIO/CT18/FF/2026/54713 A. Therapeutic Agent: [225Ac]-barecetamab-DOTA (ATNM-400) B. Imaging Agent: [89Zr]-barecetamab-DFO	M/s. ABX CRO India Private Limited.	The firm presented the proposal to conduct Phase I clinical trial titled "Phase 1 trial of a Novel HER3 Antibody Targeted Radiotherapy in Patients with Metastatic Castration Resistant Prostate Cancer." vides Protocol No. ATNM-400-1301, Version 1.0 (India) dated 19.02.2026. The committee noted that ATNM-400 consists of a fully human anti-HER3 monoclonal antibody (mAb) barecetamab labeled with the alpha (α)-emitter radioisotope [225Ac], using DOTA as a Chelator and principally when ATNM-400 binds to HER3 expressing tumor tissue, the α radiation emitted from [225Ac] causes irreversible double-strand DNA breaks which will lead to tumor cell death. The firm presented the data for non-clinical, clinical and chemistry manufacturing and control for the proposed drug product. The committee also noted that subject study is divided into three parts: Part-A: Imaging Lead-in (Prior to dosing with ATNM-400, up to 10 patients will be undergo a dosimetry and PK assessment using [89Zr]-barecetamab-DFO as a surrogate imaging agent for ATNM-400), Part-B: Dose escalation (The confirmed (1.0 µCi/kg), or adjusted, starting dose of ATNM-400 will be administered in an escalated manner using a traditional "3+3" study design) and Part-C: Dose Expansion (to further evaluate the safety, preliminary efficacy of ATNM-400, and selection of the Recommended Phase 2 Dose(RP2D). After detailed deliberation, the committee recommended for grant of permission to conduct the Phase-1 clinical trial (Part-A: Imaging Lead-in only) as per the presented protocol subject to the following conditions:

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			1. The firm shall constitute an independent Drug Safety Monitoring Board (DSMB) and submit periodic safety assessment reports to CDSCO. 2. Study report of Part-A: Imaging Lead-in shall be submitted to CDSCO for evaluation by the committee before initiation of Part-B: Dose Escalation and Part-C: Dose Expansion.
4.	BIO/CT04/FF/2026/54468 Actinium 225 (Ac-225) + Lintuzumab Solution for intravenous infusion	M/s. ABX CRO India Private Limited.	The firm presented the proposal to conduct Phase I clinical trial titled "Phase 1 Study of Safety and Tolerability of Lintuzumab-Ac225 in combination with Pembrolizumab (PEM) or Nivolumab (NIVO) in adult patients with recurrent locally advanced or metastatic Squamous cell cancer of the head and neck (HNSCC), non-small cell lung cancer (NSCLC), colorectal cancer (CRC) with high microsatellite instability (MSI) and Glioblastoma multiforme (GBM). Protocol no. AA-ST-01 Version 1.0 (India) dated 19 Dec-2025. The committee noted that the combination of Ac225-lintuzumab-DOTA with Pembrolizumab or Nivolumab will deplete immunosuppressive MDSCs and synergize with anti-PD1 checkpoint inhibitors to increase effector T-cell and enhance T-cell antitumor activity of Pembrolizumab and Nivolumab, and thus improve treatment outcomes compared with PD-1 blockade alone. The firm presented the data for non-clinical, clinical and chemistry manufacturing and control for the proposed drug product. After detailed deliberation, the committee recommended the following changes in the study protocol: 1. The proposed protocol shall

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			exclusively include either Nivolumab or Pembrolizumab as part of the combination therapy regimen. 2. To include a control arm with either Nivolumab/ Pembrolizumab in the study protocol. 3. The definition of Glioblastoma needs to be updated as per the recent WHO definition including the wild type status of the tumor. 4. The firm shall constitute an independent Drug Safety Monitoring Board (DSMB) and submit periodic safety assessment reports to CDSCO. Accordingly, the firm shall submit the revised protocol to the CDSCO for further evaluation by the committee.