Recommendations of the SEC meeting to examine IND proposals, made in its 23rd meeting held on 27.05.2022, 12:00noon at CDSCO, HQ New Delhi, through Webex (Videoconference):

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
1.	**F. No. IND/CT/22/000023** **NRC-1111**	**M/s Natco Pharma Limited**	Firm did not turn up for the presentation.
2.	**F. No. IND/CT/22/000036** **AB001**	**M/s Vopec Pharmaceuticals Private Limited**	The firm presented their proposal to conduct Phase I clinical trial study alongwith preclinical data before the committee. After detailed deliberation, the committee recommended that, the firm should present the details of in-vitro, in-vivo study data including, Pharmacokinetics, Pharmacodynamic (PK/PD) data, micronucleus test data, etc. as per requirements to consider the matter further.
3.	**F. No. IND/CT/22/000038** **AUR105**	**M/s Aurigene Discovery Technologies Limited**	The firm presented their proposal to conduct Phase I clinical trial study alongwith preclinical data before the committee. The firm presented in vitro data, toxicology studies, Dose Escalation studies, dose limiting study data alongwith the protocol for the proposed study. After detailed deliberation the committee recommended for grant of permission to conduct the phase I clinical trial for three cohorts i.e. 50 mg, 100 mg & 200 mg doses. The assessment of PK should be one of the primary endpoints. The firm should submit the results of the study for consideration by the committee for extending the study in cohorts of higher doses.
4.	**F. No. IND/CT/22/000039** **PNB 028**	**M/s Veeda Clinical Research Limited**	The firm presented their proposal to conduct Phase I clinical trial study protocol amendment Protocol No. 20-VIN-0570, Version no. 02 dated 01.Jun.2021 before the committee. During the presentation, the firm informed that earlier CDSCO has granted Phase I CT NOC vide CT NOC No. CT/ND/68/2018 dated 14.01.2019 and the proposed protocol is

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			identical to that which was approved earlier. After detailed deliberation, the committee recommended that the firm should submit a declaration that the present protocol (Protocol No. 20-VIN-0570, Version no. 02 dated 01.Jun.2021) is identicalto the earlier approved protocol (Protocol No. 0135-17, Version no. 1.1 dated 21.02.2018) to CDSCOfor taking action in the matter.
5.	**F. No. IND/CT/22/000041** **HRF-10071**	**M/s Lambda Therapeutic Research Limited**	The firm presented their proposal to conduct Phase I clinical trial study protocol alongwith preclinical data before the committee. Therefore, the committee recommended for grant of permission to conduct the trial on atleast 16 healthy subjects.
6.	**F. No. 12-02/21-DC** **PDP-117**	**ICMR & M/s Emami Ltd, Kolkata**	The firm presented their proposal for protocol amendment in light of adverse event occurred during the trial before the committee. The committee opined that the concerned subject is already out of the clinical trial. After detailed deliberation the committee advised that the applicant should approach the Ethics committee to take necessary action in the matter.
7.	**File. No: BIO/CT/20/000137** **Inactivated Chikungunya Virus Vaccine**	**M/s Bharat Biotech International Limited, Hyderabad**	The firm presented its proposal for amendment in approved clinical trial protocol of Phase II/III trial of Inactivated Chikungunya Virus Vaccine before the committee. After detailed deliberation, the committee recommended for approval of the amendments in Phase II/III trial proposed by the firm except amendments in change in secondary objective to evaluate seroconversion, prohibited medications (for use of licensed vaccines) and subject information & informed consent in trial protocol.