

Recommendations of the SEC meeting to examine IND proposals, made in its 21th meeting held on 28.03.2022, 12:00 noon at CDSCO, HQ New Delhi, through Webex (Video conference):

Age nda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	F. No. IND/CT/22/000013 GRC 54276	Glenmark Pharmaceutical s Ltd.	The firm presented their proposal to conduct Phase I clinical trial along with the protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I clinical trial. Further, firm should submit the results of Phase Ia clinical trial data to CDSCO for deliberation before proceeding to the Phase Ib clinical trial.
2.	F. No. IND/CT/22/000017 AUR 101	M/s Aurigene Discovery Technologies Limited	The firm presented their proposal to conduct Phase II clinical trial along with the protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase II Clinical trial subject to the condition that firm should monitor the lipid profile at the screening visit and at the last visit for all the subjects.
3.	F. No. IND/CT/20/000012 Desidustat	M/s Zydus Life Sciences Ltd	The firm presented their proposal to conduct Phase IV clinical trial along with the protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV Clinical trial.
4.	F. No. IND/CT/21/000028 GRC 17536	M/s Glenmark Pharmaceutical s Ltd.	The firm presented their proposal for amendment in the Phase II clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of approval for amendment in clinical trial protocol vide Clinical Study Protocol GRC 17536-206 Version 2.0 dated 18.06.2021.

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
5.	F. No. IND/MA/19/000009 Remogliflozin and Remogliflozin + Metformin Fixed Dose Combination	M/s Glenmark Pharmaceuticals Ltd.	The firm presented their proposal for amendment in the PMS study protocol before the committee. After detailed deliberation, the committee recommended that the firm should present the PSUR, ADR and SAE data, prospective interim data of 1500 patients after completion of 12 months follow up to CDSCO for further consideration.
6.	F. No. ND/CT/21/000043 Levonadifloxacin Intravenous Injection	M/s Wockhardt Limited	The firm presented their proposal for amendment in Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of approval of the protocol amendment in clinical trial protocol no: WOC/LEV/CT-01/21; Version No.: 02; Date: 08.09.2021.
