Recommendations of the SEC meeting to examine IND proposals, made in its 35th meeting held on 03.05.2023, 12:00 Noon at CDSCO, HQ New Delhi, through Webex (Video Conference):

Sr.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	F. No. IND/CT/23/000029 Nor-Ursodeoxycholic Acid 1500 mg Tablets	M/s Shilpa Medicare Limited	The firm presented the preclinical studies data & results of Phase I clinical trial alongwith the justification for Phase II Clinical trial waiverand the protocol for Phase III clinical trial before the committee. After detailed deliberation, the committee noted the results of Phase I clinical study & agreed to the firm's request. Further, the committee recommended for grant of permission to conduct the Phase III Clinical trial as per the presented protocol with following conditions- 1. The firm should revise the primary endpoints to include valid prognostic indicators as a composite endpoint. 2. Accordingly, the Sample size should be recalculated. Hence, the firm should submit the revised protocol to CDSCO for further consideration.
2.	F. No. IND/CT/22/000008 (+) -Alpha - Dihydrotetrabenazine ({+}-α -DHTBZ) 5 mg, 7.5 mg, 10 mg, 15 mg and 22.5 mg powder	M/s Synapse Labs Pvt. Ltd	The firm presented results of Phase I clinical trial before the committee. After detailed deliberation, the committee noted the results of Phase I clinical study & agreed to the firm's request.
3.	F. No. IND/CT/23/000027 Dihydrotetrabenazine ({+}-α -DHTBZ) 15 mg powder	M/s Synapse Labs Pvt. Ltd	The firm presented its proposal to conduct bioavailability study before the committee.

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			After detailed deliberation, the committee recommended for grant of permission to conduct the bioavailability study as per the presented protocol.
4.	F. No. IND/CT/22/000027 AUR103 25, 50 mg capsules	M/s Aurigene Oncology Limited	The firm presented the results for the first 3 cohorts of AUR103 i.e. (25 mg BID, 50 mg BID & 100 mg BID) of Phase-I clinical trial and requested to grant permission for next cohorts of higher dose levels i.e. (200 mg BID and 400 mg BID) for phase I clinical trial before the committee. After detailed deliberation, the committee noted the results of first 3 cohorts of AUR103 Phase I clinical study & agreed to the firm's request. Accordingly, the committee recommended for grant of permission to conduct the next cohorts of AUR103 Phase I clinical trial as per the protocol presented by the firm.
Biological Division			
5.	F. No. BIO/CT/19/000032 RUTI® Therapeutic vaccination as adjuvant of Tuberculosis chemotherapy	M/s Zydus Lifesciences Ltd.	The firm presented amendment in the protocol for Phase II b Clinical trialof Inactivated Therapeutic Tuberculosis Vaccine (RUTI Vaccine) before the committee. After detailed deliberation, the committee recommended for grant of approval for the amendment in Phase II b clinical trial protocol vide protocol No. RUTIP2-2019-01, version 03 dated 12.01.2023 with the condition to change the frequency of DSMB review to three weeks intervals instead of 06 months as proposed. Accordingly, the firm should submit revised Phase IIb clinical trial protocol to CDSCO for further consideration.