Recommendations of the SEC meeting to examine IND proposals, made in its 33rd meeting held on 13.03.2023, 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. ND/CT/23/000003 AUR107 5 mg and 20 mg tablets.	M/s Aurigene Discovery Technologies Limited	The firm presented its proposal to conduct Phase I clinical trial along within-vitro and in-vivo preclinical data before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I Clinical trial as per the presented protocol.
2.	F. No. ND/CT/22/000064 AKP-11 Ointment	M/s ICBio Clinical Research Pvt. Ltd	In light of earlier SEC recommendation dated 02.02.2023, the firm presented its proposal to conduct Phase II clinical trial along with the preclinical data, Phase I clinical study report conducted in Australia along with justification for the queries raised by the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase II Clinical trial as per the protocol presented by the firm.
3.	F. No. 12-75/14-DC (Pt. C) Desidustat50 mg and 100 mg tablet	M/s Zydus Lifesciences Limited	The firm presented its proposal for discontinuation of the Phase I study on the food effect bioavailability study entitled “An open label, randomized, single-treatment, two-period, two-conditions (fed vs fasting), two-sequence, crossover, single dose oral food effect bioavailability study of Desidustat (ZYAN1) 50 mg and 100 mg tablet in healthy adult male and female subjects”. The committee noted that, there is significant effect of food on AUC and C_{max} with 50 mg Desidustat and there is no need to conduct study with 100 mg dose. After detailed deliberation, the committee noted the results & agreed to the firm’s request.

Sr.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
4.	F. No. IND/CT/21/000028 GRC 17536	M/s Glenmark Pharmaceutical Ltd.	In light of earlier SEC recommendation dated 10.10.2022, the firm presented report regarding discontinuation of study due to futility for efficacy of GRC 17536 before the committee. After detailed deliberation, the committee noted the results & agreed to the firm's request.
5.	F. No. 12-11/17-DC Arimoclomol	M/s Covance India Pharmaceutical Services Pvt. Ltd	The firm did not turn up for the meeting.
Biological Division			
6.	F. No. BIO/CT04/FF/2022/34269 NM8074	M/s Ablenio Sciences Private Limited	The firm presented the protocol to conduct "A Phase II, Open-Label Study of NM8074 in Patients with Atypical Hemolytic Uremic Syndrome (aHUS)" vide protocol number NM8074-aHUS-401 Version 1.0, 10 October 2022. After detailed deliberation, the committee recommended the following changes in the protocol: 1. Clear inclusion criteria should be established i.e. confirmed diagnosis for aHUS. 2. Age group of the patients. 3. Lab parameters for complement mediated aHUS to be defined. 4. Under Schedule of Assessments: aHUS Symptomology Assessments should be clarified. Accordingly, the firm should submit revised protocol for further deliberation before the committee.