

Recommendations of the SEC meeting to examine IND proposals, made in its 28th meeting held on 10.10.2022, 12:00 Noon at CDSCO, HQ New Delhi, through Webex (Video Conference):

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	F. No. IND/MA/21/000010 2DG (2-Deoxy-D-Glucose) 2.34 g and 5.85 g sachet	Dr. Reddy's Laboratories	The proposal was deferred as per request of the firm.
2.	F. No. IND/CT/21/000028 GRC 17536 Capsule – 30 mg and 90 mg	M/s Glenmark Pharmaceutical Ltd.	The firm presented report regarding discontinuation of study due to futility for efficacy of GRC 17536 before the committee. After detailed deliberation, the committee recommended that the firm should submit final clinical trial report along with details of patients who discontinued or terminated the study for further review by the committee.
Biological Division			
3.	F. No. BIO/CT/22/000076 NM807440mg/ml	M/s Ablenio Sciences Pvt. Ltd.	The firm presented the protocol to conduct “A Phase II, Open-Label Study of NM8074 in Patients with Paroxysmal Nocturnal Hemoglobinuria (PNH)” vide protocol number Protocol Number: NM8074-PNH-103 Version Number: 2.0 Date: 25 August 2022 along with preclinical studies conducted in rhesus and Phase I study results conducted in USA. After detailed deliberation, the committee recommended to conduct the Phase II clinical trial as per the presented protocol with the condition that the firm should follow up the patients to 6 weeks at least instead of 3 weeks for better assessment of red cell transfusion requirements, stabilization of Hb level and infection rates.