

Recommendations of the SEC (Investigational New Drugs) made in its 08th /24 meeting held on 09.09.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
IND Division			
1.	<p>File no. IND/CT/22/000023</p> <p>Drug Name: NRC-1111</p> <p>Strength: 1 mg, 5 mg, 10 mg, 25 mg, 50 mg and 100 mg Tablet, Oral, once daily</p>	M/s. Natco Pharma Limited	<p>The firm presented their amended protocol no. NAT11P1 version no.4 dated June 27, 2024 before the committee</p> <p>After detailed deliberation, the committee has recommended that,</p> <ol style="list-style-type: none"> 1) Minimum three patients should be enrolled in each cohort study. 2) The firm should constitute DSMB. 3) The firm should submit the DSMB report of each cohort to CDSCO for further deliberation in SEC. 4) With reference to proposed protocol amendment, the committee did not agree for the following changes- <ol style="list-style-type: none"> a) Inclusion criterion for hemoglobin level has been changed to 9 g/dL. b) Patients with clinically manifest diabetes mellitus (clinical signs or with fasting glucose > 140 mg/dL or 7.8 mmol/L), history of gestational diabetes mellitus or documented steroid-induced diabetes mellitus. c) Bicarbonate and Thrombin time test parameters have been omitted. <p>Accordingly, the Firm to submit revised protocol to CDSCO for further review by the committee.</p>
Biological Division			
2.	BIO/CT04/FF/2024/42825	M/s. Ablenio Sciences Private Limited	The firm presented the protocol to conduct "A Phase II, Open-Label Study of NM8074 in Patients with

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	NM8074		<p>Immunoglobulin A Nephropathy (IgAN)", Protocol Number: NM8074-IgAN-602, Version Number: 1.0 Dated: 25 March 2024.</p> <p>After detailed deliberation, the committee recommended the following changes in the protocol:</p> <ol style="list-style-type: none"> 1. The firm should include another cohort of 10mg/kg 2. The sample size should be increased based on statistical calculation. 3. The inclusion and exclusion criteria should be revised considering all clinical parameters associated to the study. <p>Accordingly, the firm should submit revised protocol to CDSCO for further deliberation before the committee.</p>
3.	BIO/CT04/FF/2024/43211 NM5072	M/s. Ablenio Sciences Private Limited	<p>The firm presented the protocol to conduct "A Phase II, Open Label, Multi-Dose Study of NM5072 in Subjects with Paroxysmal Nocturnal Hemoglobinuria (PNH)" vide Protocol Number: NM5072-PNH-109, Version Number: 1.0 Dated: 25 April 2024.</p> <p>After detailed deliberation, the committee recommended the following changes in the protocol:</p> <ol style="list-style-type: none"> 1. Inclusion criteria of patients should clearly define the category of PNH i.e. classic, PNH with other associated mutations or asymptomatic. 2. The study design should mention whether the standard of care viz. transfusion request, C5 convertase binders, anti thrombotics, potential candidate for PBSC transplant etc to be provided to the participants. If not, it has to be ethically justified. 3. Follow up interval should be clearly defined. 4. PK monitoring parameter should be revised by considering complete ADME. 5. Protocol for assessment of vital organ like liver, kidney etc and to

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			<p>be provided as they are most commonly involved in thrombotic attacks.</p> <ol style="list-style-type: none"> 6. Patients with immunosuppressant drugs and high doses of systemic corticosteroids, patients with liver dysfunction should be excluded from the study. 7. Risk mitigation strategy should be mentioned in the protocol. 8. The assessment of Antidrug antibodies should be included in the secondary endpoints from exploratory endpoint. <p>Accordingly, the firm should submit revised protocol to CDSCO for further deliberation before the committee.</p>