

Recommendations of the SEC (Investigational New Drugs) made in its 09th/24 meeting held on 07.10.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
IND Division			
1.	IND/CT/23/000021 AUR108 Indication: Relapsed Advanced Lymphoma (ASHA-1)	M/s. Aurigene Oncology Limited	Firm has submitted an application for Amendment in the approved Phase I study Protocol AUR108-101 from Version No. 1.0 dated 13.03.2023 to Version No. 3.0 dated 30.07.2024 and requested SEC meeting for approval to include Chronic Lymphocytic Leukemia (CLL) patients in the study. After detailed deliberations, the committee did not agree for the proposed amendment to include Chronic Lymphocytic Leukemia patients in the study as this is additional new indication.
2.	IND/CT/24/000006 LNP8701 Indication: Metastatic Solid Tumors	M/s. Lupin Limited	The firm presented the Phase I Study protocol amendment before the committee. After detailed deliberation the committee recommended for approval of the amendment in Phase I clinical trial protocol vide protocol No. LRP/LNP87701/2023/003, Ver 2.0 dated 06.09.2024. Further the committee recommended for constitution of DSMB and to take approval before escalation of dose.
3.	IND/CT21/BO/2024/43193 Nafithromycin 400.00 milligram (mg) Indication: Indicated for the treatment of adults (18 years of age) with severe infections such as community-acquired bacterial pneumonia (CABP) and mild-to-moderate infections such as acute bacterial exacerbations of chronic bronchitis (AECB), acute bacterial sinusitis and pharyngitis/tonsillitis caused by the susceptible microorganisms	M/s. Wockhardt Limited	The firm presented the Phase III clinical trial study report before the committee. After detailed deliberation the committee recommended for manufacture and marketing for the following indication based on the CSR presented by the firm: Indicated for the treatment of adults (>18years old) with community-acquired bacterial pneumonia (CABP) The firm is required to submit the Phase-IV clinical trial protocol within 3 months of granting of Marketing Authorization (MA) for review by the committee.

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4.	IND/CT/20/000001 ZYBK2 Indication: Rheumatoid arthritis	M/s. Cadila Healthcare Limited	<p>The firm presented the Phase I clinical study report vide CSR No. ZYBK2 1001.CSR-01 dated 05.08.2024.</p> <p>After detailed deliberation the committee observed that there are two SAEs for which data is submitted to SAE division of CDSCO.</p> <p>Further the firm informed that they are not interested in further development of the IND.</p>