

**Recommendations of the SEC (IND) made in its 07<sup>th</sup>/25 meeting held on 05.08.2025 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>IND Division</b>			
1.	IND-12011(13)/31/2025-eoffice (Comp. no. 25829)  SCD-153 topical solution	M/s Sun Pharma Advanced Research Company Ltd.	<p>The firm has presented the revised Phase 1b clinical trial protocol entitled “A Randomized, Double-Blind, Vehicle-Controlled Study to Evaluate the Safety, Tolerability, pharmacokinetics, and Efficacy of Topically Applied SCD-153 in Patients with Alopecia Areata” vide Protocol No. SCD-153-24-01, Version A2 dated 12.06.2025 with respect to change in the formulation from Topical Solution to Topical Foam and other changes in the ongoing Phase Ib Clinical Trial protocol in Cohort 2 onwards and further request to waive off the condition mentioned in permission <i>‘to submit first cohort data to CDSCO for further review by Committee before initiation of second dose cohort’</i>.</p> <p>After detailed deliberation, the committee recommended to conduct Phase 1b Clinical trial as per revised protocol no. SCD-153-24-01, Version A2 dated 12.06.2025 &amp; recommended for waiver of condition mentioned in permission “to submit first cohort data to CDSCO for further review by Committee before initiation of second dose cohort”.</p> <p>The committee recommended to initiate cohort 2 based on review of safety data of cohort 1 by DSMB.</p>
2.	IND/CT/24/000016  ZYAT1 25 mg, 50 mg, 75 mg. Tablet	M/s Zydus Lifesciences Limited	<p>The firm has presented the interim CSR report of Phase-I MAD study in healthy subjects for 25 mg and 50 mg doses.</p> <p>After detailed deliberation, the committee has noted the result as presented by the firm and recommended to conduct the MAD study with 25 mg dose in patients with Idiopathic Pulmonary Fibrosis (IPF) as per the protocol No. ZYAT1 1001, version 03 dated 12.11.2024 presented by the firm.</p>