

Recommendations of the SEC (Investigational New Drugs (IND) made in its 05th/25 meeting held on 27.06.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	<p>BIO/CT04/FF/2025/4 9626</p> <p>M/s Sun Pharma Advanced Research Company Limited</p>	<p>SBO-154 for injection 40mg/vial</p>	<p>The firm presented their proposal of Phase I clinical trial protocol titled “A Phase 1, Multicentre, Open-Label, Multiple-Dose Study to Determine Safety, Tolerability, and Preliminary Efficacy of SBO-154 in Subjects With Advanced Solid Tumors vide Protocol Number: SBO-154-25-01 Version No. and Date: Amendment 2 (A2), dated 28th April 2025”.</p> <p>The committee noted that RCGM recommended that the preclinical toxicity studies in rodents may not be required as they are the non-relevant species for the SBO-154 and recommended for approval to conduct appropriate phase of human trial on SBO-154 based on the toxicity studies conducted in the Cynomolgus monkey. Further, the committee noted the in vitro & in vivo pharmacology studies conducted by the firm.</p> <p>After detailed deliberation, the committee recommended for approval of the proposed Phase I Clinical trial as per the protocol presented by the firm</p>