

Recommendations of the SEC meeting to examine IND proposals, made in its 26th meeting held on 23.09.2022, 02:00PM at CDSCO, HQ New Delhi, through Webex (Video Conference):

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
1.	F. No. IND/MA/21/000010 2DG (2-Deoxy-D-Glucose)	Dr. Reddy's Laboratories	The firm did not turn up for the meeting.
2.	F. No. IND/MA/19/000009 Remoglifozin 100 mg and Remoglifozin 100 mg + Metformin 500/1000 mg Fixed Dose Combination (FDC) tablets	M/s. Glenmark Pharmaceuticals Ltd	The firm presented the proposed amendment in approved patient enrolment number from 10,000 to 5000 subjects and stop further enrolment of active post marketing surveillance (PMS) study, before the Committee. After detailed deliberation, the committee recommended that the firm should submit the justification as follows: <ol style="list-style-type: none"> 1. Sample size calculation to justify Statistical significance based on the incidence of adverse drug effects. 2. Comparative table to show the incidences of adverse effects reported during the study. 3. Comparative table to show the adverse effects reported amongst other approved sodium-glucose co-transporter 2 (SGLT2) inhibitors (Canagliflozin, Empagliflozin and Dapagliflozin) with proposed FDC. 4. Firm should submit the world wide safety data of SGLT2 inhibitors in light of the adverse effects reported during the study. 5. Details of the patients followed up physically/telephonically by the firm.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
3.	F. No. IND/CT/22/000003 Intravesical SN-38 Lipid Suspension	M/s. Intas Pharmaceuticals Limited	<p>The firm presented the Phase II Clinical trial protocol amendment to clearly include the patients who have already been treated with radiotherapy, chemotherapy and surgery in the protocol, before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of approval for the amendment in Phase II clinical trial protocol vide Clinical Study Protocol 0451-21, Version 1.2 dated 07.05.2022.</p>
4.	F. No. 12-02/22-DC(Pt-05) ZRC-3306 Anti-PCSK9 product	M/s Zydus Lifesciences Limited	<p>The firm did not turn up for the meeting.</p>