

**Recommendations of the SEC (Investigational New Drugs) made in its 04<sup>th</sup>/24 meeting held on 22.04.2024 at CDSCO (HQ), New Delhi:**

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>IND Division</b>			
1.	IND/CT/19/000010 TRC 160334	M/s. Torrent Pharmaceuticals Ltd.	<p>The firm presented the Phase II clinical study report and concluded that treatment with TRC160334 failed to be fair better in comparison to placebo treatment in primary and secondary end points and decided to discontinue further development of this product.</p> <p>After detailed deliberation, the committee noted the data and observed that there were no SAE related to the investigational drug.</p>
2.	IND/CT/24/000002 Ferroquine + ZY-19489	M/s. Zydus Lifesciences Limited	<p>The firm presented the response to the 2<sup>nd</sup>/24 SEC recommendations and requested for grant of permission to conduct Phase I Clinical trial.</p> <p>After detailed deliberation, the committee recommended that Phase I trial for concurrent use of these investigational new drugs should be allowed only after marketing authorization of individual drugs.</p>
3.	IND/CT/23/000079 AUR 109	M/s. Aurigene Oncology Limited	<p>The firm presented the response to the 40<sup>th</sup> SEC recommendations and requested for grant of permission to conduct Phase II Clinical trial.</p> <p>After detailed deliberation, the committee recommended to conduct Phase I clinical trial with the aim to have PK, PD, toxicity and to find optimum dose in the Indian population.</p> <p>Accordingly, firm may submit Phase I clinical trial protocol to CDSCO for further review by SEC.</p>
4.	IND/CT/24/000005 AUR 104	M/s. Aurigene Oncology Limited	<p>The firm presented 2<sup>nd</sup> /24 SEC Query response for the conduct of Phase II Clinical trial.</p> <p>After detailed deliberation, the committee recommended for the conduct of clinical trial as per the protocol presented by the firm with the condition that the firm should submit the data after first two cohorts to CDSCO for further deliberation before the committee.</p>

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
5.	IND/CT/24/000024 AB001 Tablets	M/s. Vopec Pharmaceuticals Pvt. Ltd.	The firm presented the proposal to conduct Phase II clinical trial.  After detailed deliberation, the committee opined that the protocol design submitted by the firm is not appropriate. Accordingly, firm should submit the Indication wise revised protocol to CDSCO for further deliberation before the committee.
6.	IND/CT/24/000031 RP-12146 Tablets 100 mg	M/s. Raptim Research Pvt. Ltd.	The firm presented the proposal to conduct Phase II clinical trial.  After detailed deliberation, the committee recommended that the firm should submit data of preclinical toxicity studies conducted at GLP certified testing facility and the firm should submit protocol for Phase I clinical trial study to CDSCO for review by SEC.
7.	IND/CT/21/000030 MSP008-22	M/s. Clinixel Life Sciences Pvt. Ltd.	The firm presented the proposal for grant of approval for amendment in the Protocol No.: Clinixel-GBL-003 (Protocol Version 2 & 3) (Phase I clinical trial). The committee recommended the following: <ol style="list-style-type: none"> <li>1. The protocol amendment shall be granted after verification of Phase I data generated.</li> <li>2. The firm is required to submit permission (TL) obtained from CDSCO for the manufacture of clinical trial batches.</li> </ol>