

Recommendations of the SEC (Renal) made in its 02nd/25 meeting held on 18.02.2025. at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/10/25 Online Submission (47645) LNP023	M/s Novartis Healthcare Private Limited	<p>The firm presented phase 2a clinical study protocol no. CLNP023A2201 version number: 00 (Original Protocol) dated:28 Aug 2024.</p> <p>After detailed deliberation, the committee observed following points.</p> <ol style="list-style-type: none"> 1. Details of proof of concepts based on present study is planned need to be available. 2. The parameters for coagulation profile are was not mentioned in the exclusion criteria of the protocol while screening the patients. 3. Committee opined that justification of exposing the patients to invasive procedure (biopsy) is not clear; moreover, it seems procedure is without any clear therapeutic advantage. 4. It is not clear how to define inadequate biopsy and what action to be taken if it is inadequate. Repeat biopsy seems to be difficult in such cases 5. Committee observed that diagnostic biopsy specimen can be used for histopathology examination relevant to the

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			<p>study, instead of biopsy examination at baseline.</p> <p>6. It has been observed that patients are subjected to many investigations like Exploratory Transcriptomics, Multiparametric renal magnetic resonance imaging (MRI), many biomarker, potential predictive markers, biomarkers of tubular injury and genetics studies..etc which are not relevant to the progress of the diseases and mechanism of action & effect of this drug.</p> <p>Looking to these investigations it seems the objectives and methodology are not focused.</p> <p>7. It was mentioned that Hypersensitivity as a excluding point but details of these causes were not highlighted.</p> <p>8. Published study or Phase-II study report of present firm of Iptacopan Mesangial C3c deposition needs to be specified. Further, published study of Non clinical /Animal study data on Iptacopan with change in Mesangial C3c deposition and evidence that changes in mesangial c3c deposits have any bearing on the hard outcomes (egfr, ESKD, mortality) in patients with IgAN. may also be provided.</p>

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			Keeping in view of the above points committee opined that the firm should submit a revised protocol with detail methodology aliening with the specific objectives for further review by the committee.