

Recommendations of the SEC (Ophthalmology) made in its 49th meeting held on 22.09.2021 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Introductory remarks			
FDC Division			
1.	FDC/MA/20/000197 Brinzolamide 10mg + Brimonidine Tartrate 1.0mg I.P. Ophthalmic Suspension	M/s Akums	In light of earlier SEC recommendation dated 23.02.2021, the firm presented ocular toxicity study data and Phase III CT protocol before the committee. The committee noted that the combination is already approved in Japan and difference in the formulation is w.r.t the preservative. After detailed deliberation, committee opined that: 1. Patients with one-eyed patients should be excluded from the study. 2. Dosage administration should be one drop twice a day. 3. Study design should be stated appropriately and sample size should be calculated accordingly. In view of above, Committee recommended that firm should submit the revised Phase III CT protocol to CDSCO for approval.
2.	FDC/MA/20/000144 Tropicamide IP 0.2mg + Phenylephrine Hydrochloride IP 3.1mg + Lidocaine Hydrochloride	M/s Entod Pharmaceuticals	In light of the earlier SEC recommendations dated 23.02.2021 & 24.02.2021, firm presented the Phase IV CT results for the first 25 patients. After detailed deliberation, the committee recommended that the firm may continue the Phase IV CT study on the remaining patients and present the trial report before the committee. Committee also recommended that the firm should use validated pain scale additionally on remaining number of patients.
GCT Division			
3.	CT/60/21-DCG(I)	M/s IQVIA	The firm presented the proposed phase III clinical study protocol no. OPT-302-1004 before the Committee. Assessment of risk versus Benefit

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			<p>to the patient: The safety profile of the drug from pre-clinical toxicological studies and clinical studies, may justify the conduct of the study.</p> <p>Innovation vis –a- vis exiting therapeutic: The primary objective of the study is to determine the efficacy of intravitreal 2.0 mg OPT-302 when administered in combination with intravitreal 0.5 mg Ranibizumab, in participants with neovascular AMD.</p> <p>Unmet Medical need in the country: The test drug may be an alternative treatment option for subjects with neovascular AMD.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the trial in its presented form with the condition that the firm should submit the safety data of 10% (or 100 no.) of participants (along with DMC report) for review by the Committee for further continuation of the trial.</p>
4.	CT/80/21	M/s Cliantha	<p>The firm presented the Phase IIa clinical trial proposal before the committee.</p> <p>Assessment of risk versus benefit to the patients- The safety profile of the study drug from preclinical and clinical studies justify the conduct of the trial.</p> <p>Innovation vis-a-vis existing therapeutic- To evaluate the efficacy of the ‘next generation’ TGF-β2-selective antisense oligonucleotide ISTH0036 in treatment naïve and in previously treated patients with neovascular age-related macular degeneration (nAMD) and diabetic macular edema (DME) with severe Non proliferative (NPDRP) and mild proliferative diabetic retinopathy</p>

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			<p>(PDRP)</p> <p>Unmet medical need in the country- The test drug is to be used in neovascular age related macular degeneration (nAMD) and diabetic macular edema (DME) with severe Non proliferative (NPDRP) and mild proliferative diabetic retinopathy (PDRP).</p> <p>After detailed deliberation the committee recommended for grant of permission to conduct the study with the condition that:</p> <p>The firm should submit safety and efficacy data of the first 03 subjects from each study arm for review by the Committee prior to further enrollment of subject in the study (12 remaining subjects).</p>
5.	CT/61/21-DCG(I)	M/s IQVIA	<p>The firm presented the proposed phase III clinical study protocol no. OPT-302-1005, Version: 1.0 dated 16-Dec-2020 before the Committee.</p> <p>Assessment of risk versus benefit: The safety profile of the proposed IP-OPT-302 from pre-clinical toxicological studies and clinical studies, may justify the conduct of the study.</p> <p>Innovation vis-a-vis existing therapeutic: The primary objective of the study is to to determine the efficacy of intravitreal 2.0 mg OPT-302 when administered in combination with intravitreal 2.0 mg Aflibercept, in participants with neovascular AMD.</p> <p>Unmet Medical need in the country: The proposed Phase III global study is to assess if there are regional differences in the visual benefit achieved by the addition of IP-OPT-302 to standard of care anti-VEGF-A therapy.</p> <p>After detailed deliberation, the committee recommended for grant</p>

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Medical Device Division			
6.	CT/MD/2021/36849	M/s Biotech Vision Care Pvt. Ltd.	The firm presented the proposed phase IV study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed study.