**Recommendations of the SEC (Ophthalmology) made in its 60th meeting held on 25.11.2022 at CDSCO (HQ), New Delhi:**

| S.No. | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| **Biological Division** | | | |
| 1. | BIO/CT/20/000094<br><br>Aflibercept Injection 40mg/ml | M/s. Bayer Pharmaceuticals Pvt. Ltd. | The firm presented the protocol amendment for conduct of Phase IV clinical trial titled "A Phase IV interventional post approval trial to assess the safety of intravitreal Aflibercept for the treatment of diabetic macular edema (DME) in patients in India" version 2.0 dated 07.04.2022.<br><br>After detailed deliberation, the committee recommended for approval of the protocol amendment as presented.<br>NB: Dr. Somesh did not participate in the deliberation. |
| 2. | BIO/CT/22/000087<br><br>Aflibercept 40 mg/mL Solution for injection | M/s. Shilpa Biologics Pvt. Ltd | The firm presented the protocol for conduct of clinical trial titled "A prospective, multi-centre, randomized, double blind, parallel, active controlled Phase III study to compare the efficacy, safety, and immunogenicity of Aflibercept of Shilpa Biologicals Private Limited (SBPL) with EYLEA® (Aflibercept) of BayerAG in subjects with neovascular age-related macular degeneration (wet AMD)" Protocol Number: CBCC/2022/011, version 3.0, 17-Oct-2022.<br><br>After detailed deliberation, the committee recommended for conduct of the proposed clinical trial subject to following conditions:<br>1) The firm should provide standard of care to the study subject for the other eye during the study.<br>2) The study drug should be provided by the firm for 4 to 6 cycles after completion of trial.<br>Accordingly, the firm should submit revised protocol to CDSCO with the inclusion of above conditions.<br>NB: Dr. Purvi Bhagat did not participate in the deliberation. |
| 3. | BIO/IMP/22/0000542 | M/s. Sandoz | In light of earlier SEC recommendation dated 01.09.2022, the firm presented justification for approval of DME as additional indication on the basis of Indian patient exposure in the global |

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| | Brolucizumab | | study data as well as safety data of ongoing Phase IV study in nAMD indication and real world safety data.<br><br>Committee noted that the drug is approved in EU, USA, Japan and other 52 countries for the proposed indication and no new safety signal was observed. The drug is approved & marketed in India for nAMD since more than 2 years.<br><br>After detailed deliberation, the committee recommended for grant of permission for the additional indication of Diabetic Macular Edema (DME), subject to the condition that the firm should submit protocol to conduct Phase IV study in the proposed indication. |
| 4. | BIO/CT04/FF/2021/ 25033<br><br>Ranibizumab solution for injection 10mg/ml vial | M/s. Intas Pharmaceuticals Ltd. | The firm presented the protocol to conduct Phase IV clinical trial titled "A prospective, interventional, single arm, multi-centre, Phase IV study to assess the safety and efficacy of Ranibizumab in participants with retinopathy of prematurity" vide protocol number0248-22; Version: 1.0 Date: 30-August-2022.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct Phase IV study as per presented protocol. |
| **SND Division** | | | |
| 5. | SND/MA/22/000094<br><br>Loteprednol Etabonate Ophthalmic suspension 1% w/v | M/s. Ajanta Pharma Ltd. | The firm presented their proposal alongwith Phase III clinical trial study report of the applied drug product before the committee.<br><br>After detailed deliberation, the committee recommended for grant of manufacture and marketing permission of Loteprednol Etabonate Ophthalmic suspension 1% w/v for proposed indication by the firm. |
| 6. | SND/MA/22/000008<br><br>Dexamethasone Intravitreal Implant 0.7 mg | M/s. Allergen India Pvt. Ltd. | The firm presented their proposal alongwith justification and previous study data for waiver of active PMS study for the additional indication approved for Dexamethazone intravitreal implant 0.7mg as "For the treatment of Diabetic macular edema".<br><br>After detailed deliberation, the committee |

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| | | | recommended for waiver of active PMS study for the above mentioned additional indication. |
| 7. | SND/MA/22/000301<br><br>Pilocarpine Hydrochloride Ophthalmic solution USP 1.25 % w/v | M/s. Entod Pharmaceuticals Limited. | The firm presented their proposal of manufacture and market of Pilocarpine Hydrochloride Ophthalmic solution USP 1.25 % w/v for the indication of "For the treatment of presbyopia in adults" alongwith justification of Phase III CT waiver, comparative invitro study data, ocular toxicity study data of the applied drug product etc., before the committee.<br><br>After detailed deliberation, the committee opined that firm did not provide Indian population data of the applied drug product in the proposed new indication.<br><br>The committee recommended that the firm should conduct Phase III clinical trial in Indian population. Accordingly, the firm should submit Phase III clinical trial protocol for further review by the committee. |
| **FDC Division** | | | |
| 8. | FDC/MA/20/000197<br><br>Brinzolamide 10mg + Brimonidine Tartrate I.P. 1.0mg Ophthalmic suspension | M/s. Akums Drugs and Pharmaceutical Limited | In light of earlier SEC recommendation dated 22.09.2021, the firm presented the Phase III CT study report before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing the proposed FDC. |
| **GCT Division** | | | |
| 9. | CT/113/22<br>Online Submission (33399)<br><br>STN1010904 | M/s. Inventive International pharma | The firm presented their proposal for Phase IIa clinical study protocol number STN1010904, V2.0 IND1 20-JUN-2022 (PHANTOM Study) before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the study protocol for Phase IIa clinical study as presented. |
| 10. | CT/114/22<br>Online Submission (34056)<br><br>Faricimab/ | M/s. Roche | The firm presented their proposal for Phase IIIb/IV clinical study protocol number MR43808, version 1.0 dated 27-Jan-2022 before the committee.<br><br>After detailed deliberation, the committee recommended for proposed study with |

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| | RO6867461 | | following conditions:<br>1. The protocol title and phase should be revised for India and the study titled should be Phase IIIb rather than IIIb/IV. Accordingly, the applicant should submit India specific protocol addendum with respective study title & phase of trial.<br><br>2. The randomization of the subject should be competitive and more subjects should be randomized. |
| 11. | CT/95/22<br>Online Submission (33814)<br><br>IVIEW-1201 | M/s. Innvocept Global Solutions | The firm presented their proposal for Phase II clinical study protocol number IVIEW-1201-IN-201Version 1.0 Aug-28- 2022 before the committee.<br><br>The sponsor has informed to the committee that same protocol was approved by CDSCO on 23.07.2019 and randomized more than 40 subjects from India in the study. Meanwhile due to covid-19 pandemic, the study was prematurely terminated globally. Therefore, the sponsor has submitted fresh application with same protocol number for approval.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct Phase II clinical study in its presented form. |
| 12. | CT/80/21<br>Online Submission (21533)<br><br>ISTH-02-211 | M/s. Cliantha Research | The firm presented their proposal for protocol amendment to increase the number of patients from 24 to maximum 50 patients and waiver of earlier CT NOC condition 1.<br>The applicant had presented justification for increase in the number of patients along with global safety data before the committee.<br>After detailed deliberation, the committee recommended for increase in the number of patients from 24 to maximum 50 patients and waiver of CT NOC condition no 1 for further continuation of the trial.<br>The committee also recommended that the applicant should submit safety study data bi-annually to CDSCO for further review by the committee. |