

**Recommendations of the SEC (Ophthalmology) made in its 01<sup>st</sup>/25 meeting held on 08.01.25 at CDSCO (HQ), New Delhi:**

| S. No               | File Name & Drug Name, Strength                         | Firm Name                    | Recommendations  |
|---------------------|---|------------------------------|--|
| <b>GCT Division</b> |   |                              |  |
| 1.                  | CT/156/24<br>Online Submission (46889)<br><br>Vorolanib | M/s Synoes Health India Pvt. | The firm presented phase 3 clinical study protocol no. EYP-1901-302, Amendment 1 dated 29-Aug-2024.<br><br>After detailed deliberation, the committee opined that the firm should submit clarification of following for further review by the committee:<br>1. Rationale for using Aflibercept as loading dose.<br>2. Whether the drug is used as primary drug or maintenance drug.<br>3. Relevant data to show benefit to Indian patients.<br>4. Details of SOC in case of vision drop or large hemorrhage. |
| 2.                  | CT/155/24<br>Online Submission (46922)<br><br>Vorolanib | M/s Synoes Health India Pvt. | The firm presented phase 3 clinical study protocol no. EYP-1901-301, Amendment 1 dated 29-Aug-2024.<br><br>After detailed deliberation, the committee opined that the firm should submit clarification of following for further review by the committee:<br>1. Rationale for using Aflibercept as loading dose.<br>2. Whether the drug is used as primary drug or maintenance drug.<br>3. Relevant data to show benefit to Indian patients.<br>4. Details of SOC in case of vision drop or large hemorrhage. |