

**Recommendations of the SEC (Oncology) made in its 22<sup>nd</sup>/26 meeting held on 25.08.2026 at CDSCO HQ New Delhi:**

| S.No.                      | File Name & Drug Name, Strength                                                                                                                     | Firm Name                             | Recommendations                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
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| <b>GCT Division</b>        |                                                                                                                                                     |                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 1.                         | CT/110/26<br>Online Submission (58392)<br><br>Paxalisib Capsules, 15 mg for oral (PO) administration                                                | M/s. CBCC<br>GlobalResearch LLP       | The firm presented phase Ib clinical study protocol no. KZA-0084-ABC001 version no. 5.0 dated 07 July 2026.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Biological Division</b> |                                                                                                                                                     |                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 2.                         | E-140586<br><br>Durvalumab solution for infusion 120mg/2.4ml & 500mg/10ml (Imfinzi) and Tremelimumab concentrate for solution for infusion 20 mg/mL | M/s. Astra ZenecaPharma India Ltd.    | The firm presented the proposal for expansion of warning statement of Durvalumab solution for infusion 120mg/2.4ml & 500mg/10ml (Imfinzi) (in combination with Tremelimumab) and Tremelimumab concentrate for solution for infusion 20 mg/mL (in combination with durvalumab) approved for the indication of Hepatocellular Carcinoma for inclusion of "Registered Gastroenterologist" in addition to existing "Registered Oncologist".<br><br>After detailed deliberation, the committee did not agree to the firm's proposal and recommended that the existing warning statement shall remain unchanged.                                                                                                                                                                                                                                      |
| 3.                         | BIO/CT18/FF/2026/55757<br><br>Datopotamab Deruxtecan Powder for Concentrate for Solution for Infusion 100 mg                                        | M/s. AstraZeneca Pharma India Limited | The firm presented the proposal for the grant of approval of the following additional indication of the already approved drug product, Datopotamab Deruxtecan Powder for Concentrate for Solution for Infusion 100 mg.<br><br>"Datopotamab Deruxtecan is indicated for the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR)-mutated non-small cell lung cancer (NSCLC) who have received prior EGFR-directed therapy and platinum-based chemotherapy".<br><br>The committee noted that the subject drug product is approved in India on 16-Dec-2025 for unresectable or metastatic, hormone receptor (HR)-positive, HER2-negative (IHC 0, IHC 1+, or IHC 2+/ISH-) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease. |

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|       |                                                                                                                                                |                    | <p>The Committee further noted that the proposed indication received accelerated approval by USFDA, subject to the condition that a multicenter, randomized clinical trial (TROPION-LUNG15) be conducted to verify and characterize the clinical benefit of Datopotamab Deruxtecan in patients with EGFR-mutated non-small cell lung cancer who have experienced disease progression following treatment with osimertinib.</p> <p>After detailed deliberation, the Committee opined that the subject drug did not demonstrate significant therapeutic advancement over the current standard of care for the proposed indication, and that existing therapies are available in India for the same. The Committee therefore recommended that the firm shall submit the global Phase III clinical trial report (TROPION-LUNG15) to CDSCO for further deliberation by the Committee.</p>                                                                                                                                                |
| 4.    | <p>BIO/CT21/BO/2026/56525</p> <p>Nivolumab Concentrate for Solution for Intravenous Infusion 40 mg/4 mL &amp; 100 mg/10 mL single-use vial</p> | M/s. Lupin Limited | <p>The firm presented the proposal for grant of permission to manufacture and market the Drug Product Nivolumab Concentrate for solution for intravenous infusion (40 mg/4 mL &amp; 100 mg/10 mL) based on the results of Phase III clinical trial (LRP/LUBT022/2024/002) conducted by the firm to establish the Efficacy, Safety, Pharmacokinetic and Immunogenicity of the drug product in Locally Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC).</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market Nivolumab 40 mg/4 mL and 100 mg/10 mL concentrate for solution for intravenous infusion for the indication of Locally Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC).</p> <p>Further firm has also presented proposal for approval of additional indications by the way of extrapolation in line with indications approved for innovator product based on prescribing information.</p> <p>After detailed deliberation, the committee</p> |

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|                          |                                                                                                                                                   |                                       | <p>recommended for approval of the applied additional indications that are already approved for innovator product in India subject to the condition that firm shall conduct Phase IV study in the country for all approved indications including Locally Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC).</p> <p>Accordingly, the protocol to conduct the Phase IV study shall be submitted within three months of grant of marketing authorization permission to manufacture and market the product.</p>                                                                                                                                                                                                                                                                                                                                                            |
| 5.                       | BIO/CT04/FF/2025/49902<br><br>Pertuzumab and Trastuzumab Solution for Injection (1200 mg + 600 mg/15 mL Vial) and (600 mg + 600 mg/10 mL in Vial) | M/s. Intas Pharmaceuticals Ltd        | <p>In light of earlier recommendation dated 23.09.2025, the firm presented the amended Protocol No. 0017-25 Version No. 3.0, Dated 20.12.2025 to conduct Phase I/III clinical trial study titled “A Phase I/III, Prospective, Assessor-Blind, Randomized, Multicentre, Active-Controlled, Two-Arm, Parallel-Group, Comparative Clinical Study to Investigate the Efficacy, Safety, Immunogenicity and Pharmacokinetics of INTP78 Versus Phesgo®, Both Administered in Combination with Docetaxel, in Previously Untreated Patients With HER2-Positive Locally Advanced or Metastatic Breast Cancer”.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as per amended protocol Version No. 3.0, Dated 20.12.2025 subject to the condition that number of evaluable patients should not be less than 260.</p> |
| <b>New Drug Division</b> |                                                                                                                                                   |                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 6.                       | ND/80/2026-eoffice<br><br>Carfilzomib Sterile Lyophilized Powder for Injection 60 mg/vial (50 mL vial)                                            | M/s. Amgen technology Private limited | <p>The firm presented Phase IV clinical trial report of drug Carfilzomib Sterile Lyophilized Powder for Injection 60 mg/vial (50 mL vial) before the committee.</p> <p>After details deliberation committee considered the result of phase IV clinical trial as presented by the firm.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 7.                       | ND/123/2026-eoffice<br><br>Alpelisib tablets 50mg/150mg/200mg                                                                                     | M/s. Novartis India Limited.          | <p>The firm presented Phase IV clinical trial report of drug Alpelisib tablets 50mg/150mg/200mg (No. CBYL719CIN01, v1.0 dated 20.02.2026), before the committee.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

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|       |                                                             |                                 | After details deliberation committee considered the result of phase IV clinical trial as presented by the firm.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 8.    | ND-12011(13)/16/2026-eoffice<br><br>Tenalisib Tablets 400mg | M/s. Syngene international Ltd. | <p>The firm presented Phase II clinical trial study report (Interim report of containing safety and efficacy data of 10 Patient) Titled: “A Phase II, Multi-centre, Single-arm, Open-label Study to Assess the Efficacy and safety of Tenalisib in Patients with Metastatic Triple Negative Breast Cancer (TNBC)”. (Protocol No.: RP6530-2301) before the committee.</p> <p>After detailed deliberation, the committee noted that there is no convincing safety data presented by the firm. The committee noted that drug has only partial response, there were no patient enrollment from proposed government sites. There were concern w.r.t patient fitness during enrollment and rapid progression of underlying disease.</p> <p>The committee further observed that there is limited efficacy with the drug, which does not justify the continuation of the trial.</p> <p>Hence, committee did not recommended for further continuation of phase II clinical trial.</p> |