

**Recommendations of the SEC (Oncology) made in its 36<sup>th</sup>/25 meeting held on 03.12.2025 at CDSCO HQ New Delhi:**

| S. No                      | File Name & Drug Name, Strength  | Firm Name                                     | Recommendations   |
|----------------------------|--|---|---|
| <b>GCT Division</b>        |  |   |   |
| 1.                         | CT/84/25<br>Online Submission<br>(50220)<br><br>Lisafoclax (APG-2575)                                      | M/s IQVIA<br>RDS (India)<br>Private Limited   | In light of earlier SEC recommendation dated 29.07.2025, the firm presented phase III clinical study protocol no. APG2575CC301 version no. 2.0 dated 15 April 2025.<br><br>Now the firm presented phase I & II study report including safety data, global approval status of the drug with indication, prescribing information...etc.<br><br>After detailed deliberation, the committee didn't recommend the study protocol with patient in Newly Diagnosed Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (GLORA-2 Study) following reasons:<br><br>1. The Control arm is significantly inferior.<br><br>2. The Toxicity data is not properly addressed especially, in the context of the prevailing COVID-19 Pandemic situation. |
| 2.                         | CT/93/25<br>Online Submission<br>(50656)<br><br>Sacituzumab<br>tirumotecan                                 | M/s MSD<br>Pharmaceuticals<br>Private Limited | The firm did not turn up for the meeting.   |
| <b>Biological Division</b> |  |   |   |
| 3.                         | BIO/CT18/FF/2025/<br>51752<br><br>Durvalumab Solution<br>for Infusion 120<br>mg/2.4 mL and 500<br>mg/10 mL | M/s<br>AstraZeneca<br>Pharma India<br>Limited | The firm did not turn up for the meeting.   |
| 4.                         | BIO/CT04/FF/2025/5<br>2034<br><br>Pertuzumab Injection<br>(rDNA origin) 420<br>mg/14 mL                    | M/s Enzene<br>Biosciences Ltd.                | The firm presented the proposal to conduct a Phase IV clinical trial titled "A Phase IV, Multicenter, Open-Label, Single-Arm Evaluation of Biosimilar Pertuzumab in Indian Patients with HER2-Positive Early and Metastatic Breast Cancer", as per Protocol No. ALK47/ENZ130-PER2, Version 1.0, dated 05/09/2025.<br><br>The Committee noted that Pertuzumab Injection (rDNA origin) 420 mg/14 mL,  |

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|                           |  |  | <p>manufactured by M/s Enzene Biosciences Ltd. is currently approved only for the treatment of HER2-positive Metastatic Breast Cancer and not for HER2-positive Early Breast Cancer. As per regulatory requirements, a Phase IV clinical trial shall be conducted only for the approved indication.</p> <p>After detailed deliberation, the Committee recommended the following:</p> <ol style="list-style-type: none"> <li>1. The study shall be conducted only in the approved indication, i.e. HER2-positive Metastatic Breast Cancer.</li> <li>2. Daycare facilities shall be removed from the list of clinical trial sites.</li> </ol> <p>Accordingly, the firm shall submit the revised protocol for further evaluation by the SEC.</p>   |
| <b>New Drugs Division</b> |  |  |   |
| 5.                        | ND/MA/25/000101<br>Belzutifan tablets 40 mg          | M/s Zydus Lifesciences Limited             | <p>The firm presented the proposal for grant of permission to manufacture and market drug, Belzutifan tablet 40 mg along with BE study report and justification for local Phase-III clinical trial waiver of drug, Belzutifan tablet 40 mg before the committee.</p> <p>The Committee noted that the firm has presented single dose BE study in fasting and fed state in Indian healthy subjects.</p> <p>The committee noted that the firm has not presented detailed data wrt the clinical trials conducted on Belzutifan tablets and only presented extracts of package insert of Innovator.</p> <p>The committee is of opinion that there is lack of sufficient efficacy and safety data to prove that the dose requirement in Indian population is adequate. Further, the firm has not presented data wrt ethnic variability and South-East Asian population.</p> <p>The committee did not recommend phase III Clinical Trial waiver at this stage.</p> |
| 6.                        | ND/121/2025-eoffice<br>Neoadjuvant Chemotherapy with | IEC-I Member Secretary, IRB, Tata Memorial | The study investigator presented protocol titled” A Phase II randomized trial of Neoadjuvant Chemotherapy with or without triple oral metronomic chemotherapy and   |

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|                     | or without Triple Oral Metronomic Chemotherapy and Low-Dose Immunotherapy in resectable Locally Advanced Penile Squamous Cell Carcinoma. | Hospital, Mumbai                     | low- dose immunotherapy in resectable locally advanced penile squamous cell carcinoma, IEC Project No- 4851) (NIRVANA study, protocol version 1, Dated 13.08.2025)” before the committee.<br><br>After detailed deliberation, the committee stated that since this is an academic Clinical Trial, applicant may approach to institutional Ethics Committee for consideration.  |
| <b>SND Division</b> |  |                                      |  |
| 7.                  | SND/IMP/25/000001<br><br>Acalabrutinib Tablets 100 mg (Additional Indication)  | M/s AstraZeneca Pharma India Limited | The firm presented the proposal for grant of permission to import and market Acalabrutinib Tablets 100 mg for Proposed indication as in combination with venetoclax with or without obinutuzumab is indicated for the treatment of patients with previously untreated chronic lymphocytic leukaemia (CLL)/small lymphocytic lymphoma (SLL) along with proposed Prescribing information before the Committee.<br><br>The Committee noted that the product Acalabrutinib Tablet/Capsules 100mg is approved in India from 2019 in treatment of Chronic Lymphocytic Leukaemia (CLL)/Small lymphocytic lymphoma (SLL). Further, firm informed that the Acalabrutinib Tablet 100 mg is approved in EU, UK, Singapore etc. for Proposed indication as combination therapy.<br><br>After detailed deliberation, the Committee recommended for grant of permission to Import and market Acalabrutinib Tablet 100 mg for proposed indication.<br><br>Further, the Committee recommended to update package insert in line with Summary of Package insert (SmPC) of EU and other key countries and submit the same to CDSCO. |
| 8.                  | SND-16011(11)/105/2025 and SND/IMP/25/000036<br><br>Ribociclib film-coated tablets 200 mg  | M/s Sandoz Private Limited           | In light of earlier SEC recommendation dated 06.08.2025, firm has submitted the status of ongoing Phase IIIb clinical trial for early Breast Cancer (ADJUVANT WIDER) before the committee.<br><br>The committee noted that Ribociclib film coated tablets 200 mg is approved for the applied indication in US, UK, Australia,  |

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|       |                                 |           | <p data-bbox="884 129 1331 159">New Zealand and Switzerland etc.</p> <p data-bbox="884 203 1474 456">After detailed deliberation, the committee recommended for grant of permission for manufacture and market of Ribociclib film coated tablets 200 mg for the applied indication subject to condition that the firm should conduct Phase IV clinical trial in proposed indication.</p> <p data-bbox="884 501 1474 674">Accordingly, the firm should submit Phase IV clinical trial study protocol to CDSCO within 03 months from date of approval of the drug product for further review by the committee.</p> |