**Recommendations of the SEC (Oncology) made in its 30th/25 meeting held on 23.09.2025 at CDSCO HQ New Delhi:**

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| **GCT Division** | | | |
| 1. | CT/118/25<br>Online Submission (51292)<br><br>Izalontamab Brengitecan | M/s. Bristol-Myers Squibb India Pvt. Ltd | The firm presented phase II/III clinical study protocol no.: CA 2440008, amendment 01 version No. 1.0 dated 30-APR-2025.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following conditions:<br><br>1. More geographically distributed government sites shall be included in the study.<br><br>2. PI shall be Medical Oncologist only. |
| 2. | CT/124/25<br>Online Submission (51381)<br><br>BMS-986369 CC-99282 | M/s. Bristol-Myers Squibb India Pvt. Ltd | The firm presented phase III clinical study protocol no. CA0731003 version 1 original protocol dated 11 February 2025.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following conditions:<br><br>1. More geographically distributed government sites shall be included in the study.<br><br>2. PI shall be Medical Oncologist only. |
| **Biological Division** | | | |
| 3. | BIO/CT04/FF/2025/51076<br><br>Sacituzumab vedotin (ZRC-3328) 50 mg/ vial Powder for concentrate for solution for intravenous infusion | M/s. Zydus Lifesciences Limited | The firm presented a proposal to conduct a clinical trial titled, "A Phase 1/2, Multicenter, Study to Assess the Safety, Tolerability, Pharmacokinetics, Immunogenicity and Preliminary Efficacy of sacituzumab vedotin alone and in combination with anti-PD-1/PD-L1 monoclonal antibody in Patients with Advanced Epithelial Tumors" as per study protocol No.: SACI.25.001; Ver. No. 1.0; Dated: 14 July 2025.<br><br>After detailed deliberation, the committee recommended for grant of permission to |

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| | | | conduct the Phase 1a clinical trial only as per the protocol presented by the firm with recommendation for special monitoring of adverse events of special interest of peripheral neuropathy.<br><br>An Independent DSMB may be created for close monitoring of adverse events and patient safety.<br><br>Accordingly, firm shall submit the revised protocol to CDSCO.<br><br>Note: Dr. Kaushal Kalra did not participate in the discussion. |
| 4. | BIO/CT18/FF/2025/49563<br><br>Zolbetuximab powder for concentrate for solution for infusion 100 mg and 300 mg | M/s. Astellas Pharma India Pvt. Ltd | The firm presented the proposal for grant of permission to import and market of Zolbetuximab powder for concentrate for solution for infusion 100 mg and 300 mg for the indication "Zolbetuximab in combination with fluoropyrimidine and platinum containing chemotherapy, is indicated for the first-line treatment of adult patients with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors are Claudin (CLDN) 18.2 positive with a request for waiver of Phase III Clinical Trial in India.<br><br>The firm presented the safety and efficacy data generated from Global Clinical trial including Asian Population along with justification for the waiver of local Phase III clinical trial in India.<br><br>The Committee noted that the drug is already approved in the countries like US, UK, EU, Japan, Canada, Australia etc. and there is an unmet medical need in the country.<br><br>After detailed deliberation, the committee recommended for the grant of permission to import and market of Zolbetuximab powder for concentrate for solution for infusion 100 mg and 300 mg with a local Phase III clinical trial waiver with condition to conduct Phase IV study. |

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| | | | Accordingly, the firm should submit the Phase IV protocol to CDSCO within three months of grant of Marketing Authorisation to conduct Phase IV study in credible number of subjects across various parts of the country. |
| 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 | The firm has presented the proposal for grant of permission 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" vide protocol No. 0017-25 Version No. 1.1, Dated 09.05.2025.<br><br>After detailed deliberation, the committee recommended the following changes in the protocol:<br><br>1. The non-inferiority margin was observed to be wider than the delta of ORR in reference trial and should be narrowed appropriately and sample size should be revised accordingly.<br><br>2. The safety follow up should be done at-least for one year.<br><br>Accordingly, the firm should submit revised protocol to CDSCO for further evaluation by the committee. |
| **SND Division** | | | |
| 6. | SND/MA/24/000052<br><br>Abiraterone Acetate Tablets 1000 mg | M/s. MSN Laboratories Private Limited | In light of earlier SEC recommendation dated 09.07.2024, the firm presented the proposal for grant of permission to manufacture and market Abiraterone Acetate Tablets 1000 mg along with BE report under fasting condition and justification for CT study waiver before the committee.<br><br>After detailed deliberation, the committee |

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| | | | recommended to accept the BE report and recommended for grant of permission to manufacture and market of Abiraterone Acetate Tablets 1000 mg for the applied indication subject to condition that firm should conduct Phase IV Clinical Trial.<br><br>Accordingly, firm should submit Phase IV Clinical Trial protocol within 3 months from the date of approval of the product to CDSCO for further review by the committee. |
| 7. | SND/CT/25/000087<br><br>Lipid Based Cabazitaxel Tablets 50 mg | M/s. INTAS PHARMACEUTICALS LTD | The firm presented their proposal for grant of permission to conduct Phase I Clinical trial to evaluate the food effect on the pharmacokinetics of lipid-based Carbazitaxel tablets (50 mg) in patients with advanced solid tumors who have failed conventional therapy before the Committee,<br><br>After detailed deliberation, the committee recommended to conduct Phase I Clinical trial study as per protocol presented by the firm with the condition that patients with gastrointestinal malignancies be excluded from the study population. |
| 8. | SND/CT/25/000055<br><br>Amlodipine Tablets 10 mg (additional Indication) | M/s. Raptim Research Pvt. Ltd. | The firm requested to conduct a Phase II study of Amlodipine Tablets 10 mg to prevent metastasis and improve survival in Post-surgical non-metastasized Colorectal Cancer Patients either alone or in combination with radiotherapy and/or chemotherapy before the Committee.<br><br>After detailed discussion, the Committee opined that the firm should submit the proof of concept study data/Published literature along with safety and tolerability information to CDSCO for review by the Committee. |