**Recommendations of the SEC (Oncology) made in its 24th meeting held on 10.12.2024 at CDSCO (HQ), New Delhi:**

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| **GCT Division** | | | |
| 1. | CT/132/24 46231 Online Submission (46231) Rilvegostomig (AZD2936) Concentrate for solution for infusion 50 mg/mL (750 mg/vial) | M/s Astrazeneca | The firm presented phase 3 clinical study protocol no. D702FC00001, Version 2.0 dated 30 Jul 2024 and Local CSP - Addendum IND -1, Version 1.0 dated 26 Jul 2024.<br>After detailed deliberation, the committee recommended for grant of permission to conduct the trial with the following conditions:<br>1. PK data in Indian patients shall be generated and submitted to CDSCO<br>2. ICMR permission shall be obtained for export of biological samples for genetic testing. |
| 2. | CT/131/24 46180 Online Submission (46180) Rilvegostomig (AZD2936) Concentrate for solution for infusion 50 mg/mL (750 mg/vial) | M/s Astrazeneca | The firm presented phase 3 clinical study protocol no. D702BC00001, Version 2.0 dated 06 August 2024 and Local CSP - Addendum IND -1, Version 1.0 dated 12 Jul 2024.<br>After detailed deliberation, the committee recommended for grant of permission to conduct the trial with the following conditions:<br>1. PK data in Indian patients shall be generated and submitted to CDSCO<br>2. ICMR permission shall be obtained for export of biological samples for genetic testing. |
| 3. | CT/111/23 35951<br><br>Online Submission (35951) Daratumumab | M/s Spectrum | The firm presented Increase the number of subjects in India to 80 protocol no. BCD -264-2IDARVIVA.<br>After detailed deliberation, the committee recommended for approval of increase in number of subjects from 65 to 80 in India |
| 4. | CT/67/24 36012 Online Submission (36012) GSK4428859A (Belrestotug), GSK 4057190 (Dostarlimab) | M/s GSK | The firm presented protocol amendment 2 dated 13 September 2024 protocol no. 213823.<br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. |
| 5. | CT/16/24 41452 Online Submission (41452) GME751 (Pembrolizumab) | M/s Parexel | In light of earlier SEC recommendation dated 03.04.2024 & 04.04.2024, the firm presented safety data as asked in earlier SEC for phase III clinical study protocol no. CGME751A12301, version1.0 |

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| | | | dated24-Jul-2023.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the phase III trial as presented by the firm with following conditions:<br>1. More Govt. sites shall be included.<br>2. PI shall be Medical Oncologist only. |
| **New Drugs Division** | | | |
| 6. | ND/IMP/24/000030 Ivosidenib 250 mg film-coated tablet | M/s Servier India Private Limited | In light of earlier SEC recommendation dated 07.08.2024 and 08.08.2024, the firm presented data for unmet need of the drug, the percentage of IDH mutation in cholangiocarcinoma and survival benefits of the drug in IDH mutated cholangiocarcinoma before the committee. However, the firm did not present subset analysis data for South East Asian population.<br><br>Therefore, the committee recommended to conduct PK/PD study in Indian population. Accordingly, the firm should submit PK/PD study protocol to CDSCO for further review by the committee. |
| 7. | ND/IMP/24/000037 Tenalisib 400 mg tablet | M/s Syngene International Limited | The firm presented amendment to protocol for the Phase II Study (Protocol no. RP6530-2301, Version no. 2.00, dated 13 June 2024) before the committee.<br>The permission to conduct Phase-II clinical trial with Tenalisib tablet 400 mg in patients with metastatic Triple Negative Breast Cancer( TNBC) was granted on 29.11.2023.<br><br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. Further, the committee noted that the indication metastatic Triple Negative Breast Cancer (TNBC) has not been studied before and there is no safety and efficacy data in the said indication as per the new dose proposed by the firm (400 mg bid). Therefore, the committee recommended that the firm should submit the interim safety and efficacy data |

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| | | | generated on next 10 patients to be reviewed by the committee, before enrolling the rest of the patients in the said trial. |
| **SND Division** | | | |
| 8. | SND/MA/23/000028<br><br>Abiraterone Acetate Oral Suspension 1000mg/5ml | M/s BDR Pharmaceuticals Int Private Limited | In light of earlier SEC recommendation dated 15.05.2024, firm presented the BE protocol in fasting condition before the SEC Committee. After detailed deliberation, Committee recommended for conduct of BE study in fasting condition with following:<br>1) Protocol needs to be included the test of HbA1c, Lipid profile, ECG, CBC, LFT, KFT at the time of screening, completion of Period I & Period II. Further, sample size should be increased to 38 subjects.<br>2) Further, firm has to justify the use of Abiraterone Acetate Oral Suspension 1000mg/5ml as the Suspension is not approved anywhere in the world and Abiraterone Tablets 250mg/500mg are approved in the Country. |