Recommendations of the SEC (Oncology) made in its 24th/26 meeting held on 22.09.2026 at CDSCO HQ New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT18/FF/2025/50439 Amivantamab Solution for Injection 1600 mg & 2240 mg (Rybrevant Faspro)	M/s. Johnson & Johnson Pvt. Ltd	The firm presented the proposal for grant of approval for the following indications of the drug product Amivantamab Solution for Injection 1600 mg & 2240 mg (Rybrevant Faspro, 160mg/ml) with an alternative route of administration (subcutaneous), along with a request for a local clinical trial waiver. 1. Amivantamab (RYBREVANT FASPRO) in combination with Lazertinib is indicated for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations. 2. Amivantamab (RYBREVANT FASPRO) as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic NSCLC with activating EGFR exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy. The committee noted that the applied indications have already been approved in India for Amivantamab 350 mg/7 mL vial (50 mg/mL) for intravenous administration. After detailed deliberation, the committee recommended to submit the following: 1. Safety data from the ongoing Phase III clinical trials involving the subcutaneous formulation of the subject drug. 2. Updated safety data from the ongoing Phase II (PALOMA-2) and ongoing Phase III (PALOMA-3) studies. 3. Status of the Phase IV study for the combination therapy (Amivantamab IV in combination with Lazertinib Tablets for non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations), which was approved by CDSCO.

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			Accordingly, the firm shall submit the same to CDSCO for further evaluation by the committee.
2.	BIO/CT18/FF/2026/56916 Amivantamab Solution for Injection (Subcutaneous Injection) 2400 mg in Single dose vial of 15 mL (160 mg/ml) & 3520 mg in Single dose vial of 22 mL (160 mg/ml)	M/s. Johnson & Johnson Pvt. Ltd	The firm presented the proposal for grant of approval for the following indications of the drug product Amivantamab Solution for Injection 2400 mg & 3520 mg (Rybrevant Faspro, 160mg/ml) with an alternative route of administration (subcutaneous), along with a request for a local clinical trial waiver. 1. Amivantamab (RYBREVANT FASPRO) as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic NSCLC with activating EGFR exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy. 2. Amivantamab (RYBREVANT FASPRO) is indicated in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal-growth factor receptor (EGFR) Exon 20 insertion mutations. 3. Amivantamab (RYBREVANT FASPRO) is indicated in combination with carboplatin and pemetrexed for the treatment of patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, whose disease has progressed on or after treatment with osimertinib. The committee noted that the applied indications have already been approved in India for Amivantamab 350 mg/7 mL vial (50 mg/mL) for intravenous administration. After detailed deliberation, the committee recommended to submit the following: 1. Safety data from the ongoing Phase III clinical trials involving the subcutaneous formulation of the subject drug. 2. Updated safety data from the ongoing Phase II (PALOMA-2) and ongoing Phase III (PALOMA-3) studies.

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			3. Status of the Phase IV study for the combination therapy (Amivantamab IV in combination with Lazertinib Tablets for non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations), which was approved by CDSCO. Accordingly, the firm shall submit the same to CDSCO for further evaluation by the committee.
3.	BIO/CT04/FF/2026/56766 Durvalumab Solution for Infusion 120 mg/2.4 mL and 500 mg/10 mL	M/s. AstraZeneca Pharma India Limited	The firm presented the proposal to conduct a Phase IV clinical trial titled- "A Prospective, Multi-Center, Phase 4, Single Arm study to assess the safety and tolerability of Durvalumab in Indian patients with Limited-Stage Small Cell Lung Cancer (LS-SCLC) whose disease has not progressed following Platinum-Based Chemoradiation therapy (CRT)" vide Study code: D933QL00001, Version: 1.0 dated 04-May-2026. After detailed deliberation, the committee recommended the grant of permission to conduct the proposed Phase IV trial subject to the following conditions- 1. Clinical trial sites should be geographically distributed. 2. Sample size of the study should be increased by 10%. Accordingly, the firm shall revise the protocol and submit the same to CDSCO. Note: Dr. Kaushal Kalra did not participate in the deliberation.
4.	BIO/CT04/FF/2026/56829 Trastuzumab Injection 150mg & 440mg	M/s. Virchow Biotech Pvt. Ltd.	The firm presented the proposal for permission to conduct Phase III clinical trial "A Comparative, Randomized, Multicenter, Parallel Study to Evaluate the Efficacy, Safety Pharmacokinetic profile and Immunogenicity of VBTZM01-Trastuzumab) and Herclon (Roche Trastuzumab) in combination with Docetaxel in Patients of HER2-positive Metastatic Breast Cancer" vide Protocol no. VBTZM01-IV/2025-CT1, version 01, dated 25.11.2025. After detailed deliberation, the committee recommended the following:–

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			1. Firm may calculate the sample size for the proposed Phase III study using a statistically justified criteria and limit of non-inferiority margin. 2. The study design should be modified from an open-label to a blinded study. Accordingly, the firm shall revise the protocol and submit the same to CDSCO
New Drug Division			
5.	ND/IMP/25/000083 Camizestrant film-coated tablets 75mg	M/s. AstraZeneca Pharma India Limited	The firm presented the proposal for grant of permission for import and marketing of Camizestrant film-coated tablets 75mg,along with justification for local Phase III Clinical Trial waiver before the committee. After, detail deliberation, the committee noted that Camizestrant approved in USA, European Union, United Arab Emirates, Saudi Arabia and other countries. Further, the committee noted that this is unmet medical need and recommended for phase III CT waiver for the indication hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer upon emergence of ESR1 mutation. Accordingly, the committee recommended for grant of permission to import and market the drug Camizestrant film-coated tablets 75mg subject to following conditions: 1) The drug should be sold by retail under prescription of medical Oncologist only. 2) The firm should conduct Phase-IV clinical trial and submit the Phase IV Clinical Trial protocol within 3 months of approval of the drug to CDSCO for further review by the committee.
6.	ND/MA/26/000004 Trilaciclib for injection 300mg/vial	M/s. Hetero Labs Limited	The firm presented the proposal for grant of permission for manufacture and marketing of Trilaciclib for injection 300mg/vial,along with justification for local Phase III Clinical Trial waiver before the committee. The committee noted that Trilaciclib for injection 300mg/vial is approved in United States and China but there is no unmet

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			medical need for the proposed indication and data of Indian patients is not available to address the ethnic variability. Further, the committee noted that the firm has not presented any comparison with the already available treatment. After detailed deliberation, committee did not agree for Phase-III CT waiver. Accordingly, the firm should conduct Phase III Clinical trial and submit Phase III CT protocol to CDSCO for further review by the committee.
7.	ND/CT/26/000014 Lutetium Lu 177 vipivotide tetraxetan solution for injection or infusion 1000 MBq/mL	M/s. Novartis Healthcare Private Limited	In light of earlier recommendations dated 06.05.2026, the firm presented revised Phase-IV Clinical Trial protocol of the drug, Lutetium Lu-177 Vipivotide Tetraxetan solution for injection or infusion 1000 MBq/mL, (Protocol Number: CAAA617A0IN01, Version No: V01, dated 24-July-2026) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase IV clinical trial as per the revised protocol presented by the firm with the condition that firm should increase the sample size atleast to 80 considering that there are two cohorts of patients to be enrolled in the Phase IV trial. Accordingly, firm should submit the revised Phase IV CT protocol to CDSCO within one month. Further, firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.
SND Division			
8.	SND/11011/15/2026-eoffice Trametinib Tablets 0.5mg and 2mg	M/s. Novartis Healthcare Pvt. Ltd.	The firm presented the proposal for approval of the updated Package Insert for Trametinib Tablets 0.5 mg and 2 mg, with new ADRs based on the latest USFDA-approved Package Insert. Firm stated that Guillain-Barré syndrome (<1%) and sarcoidosis (<1%) were observed in patients treated with Trametinib in Study BRF117019. The Committee noted that Trametinib Tablets 0.5 mg and 2 mg are already approved in India since 2017. Further, it is

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			also noted that, the said updates in the Package Insert have already been approved in Australia, Canada, Singapore, Russia, the European Union (EU) and Switzerland. After detailed deliberation, the Committee agreed with the proposed inclusion of the above adverse drug reactions (ADRs) in the Package Insert of Trametinib Tablets 0.5 mg and 2 mg.