

Recommendations of the SEC (Oncology) made in its 25th/26 meeting held on 29.09.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT18/FF/2026/56705 Nivolumab 10 mg/mL concentrate for solution for infusion: 40mg, 100mg and 240mg (Brand name: Opdyta)	M/s. Bristol-Myers Squibb India Pvt. Ltd.	The firm presented the proposal for approval of following additional indication of approved drug Nivolumab 10 mg/mL concentrate for solution for infusion (40 mg, 100 mg, and 240 mg) (Opdyta®), along with a request for local clinical trial waiver based on the safety and efficacy data from Phase III clinical trial CA209-8UT (SWOG1826) conducted outside India. Proposed Indication- Classical Hodgkin's Lymphoma: Nivolumab, in combination with doxorubicin, vinblastine, and dacarbazine (AVD), is indicated for the treatment of adult and pediatric patients aged 12 years and older with previously untreated Stage III or IV classical Hodgkin lymphoma (cHL). The Committee noted that the proposed indication is approved in 38 countries, including major ICH countries such as the United States and the European Union. The committee further noted that there is no safety data available for this drug in the age group of 12-18 years of Indian patients. After detailed deliberation, the committee recommended for the approval of the proposed additional indication, subject to the condition that the firm shall conduct a Phase IV clinical trial in India with significant number of paediatric participants aged 12–18 years for the proposed indication. Accordingly, the firm shall submit the Phase IV clinical trial protocol to CDSCO within three months from the date of grant of marketing authorization permission.
2.	BIO/CT18/FF/2026/56617 Denosumab 120 mg/1mL Solution for Injection in PFS with automatic needle guard (Brand Name: Xgeva®)	M/s. Dr. Reddy's Laboratories Limited	The firm presented a proposal for grant of approval of Denosumab 120 mg/1mL Solution for Injection in PFS with automatic needle guard in addition to Denosumab 120 mg/1.7 mL Solution for Injection in vial (Brand Name- Xgeva®) which is approved in India since Aug-2017. The committee noted that the proposed

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			strength has been approved in Europe since Feb 2024. After detailed deliberation, the committee recommended for the grant of approval of Denosumab 120 mg/1mL Solution for Injection in PFS with automatic needle guard; in line with the indications approved by EMA and subject to the following conditions: 1. The firm shall conduct the active PMS study for the approved indications. 2. The firm shall include an appropriate warning regarding the presence of phenylalanine for patients with phenylketonuria on the product label including Package Insert. Accordingly, the protocol to conduct the active PMS study shall be submitted within three months of grant of approval for proposed strength.
3.	E-155432 1. Trastuzumab Lyophilized powder for injection 150 (mg) (r-DNA origin) multiple use vial (Combipack) supplied along with Bacteriostatic Water for injection containing 1.1% Benzyl alcohol. (10 mL Bacteriostatic Water for Injection will be supplied along with the product). 2. Trastuzumab Lyophilized powder for injection 440 mg (r-DNA origin) multiple use vial (combipack) supplied along with Bacteriostatic Water for injection containing 1.1% Benzyl alcohol. (2 x 10 mL Bacteriostatic	M/s. Biocon Biologics Limited	The firm presented the proposal to conduct PMS study titled as “A Multicenter, Observational, Post Marketing Surveillance to Evaluate the Safety of Trastuzumab Intravenous Infusion (Trastuzumab Lyophilized powder for injection of Biocon Biologics Limited) Administered as per the Approved Prescribing Information in the Treatment of Patients with HER2 Over expressing Adjuvant Breast Cancer, Metastatic Breast Cancer and Metastatic Gastric Cancer” vide Protocol No. BIO-TRASTU-404, Version 1 .0, Dated 15/06/2026. After detailed deliberation, the committee recommended for the grant of permission to conduct the proposed PMS study as per the protocol presented by the firm.

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	Water for Injection will be supplied along with the product).		
4.	BIO/CT04/FF/2026/57969 Nivolumab Concentrate for Solution for Infusion 10mg/mL (40mg/4mL, 100mg/10mL & 240mg/24mL)	M/s. Dr Reddy's Laboratories Limited	The firm presented the proposal to conduct Phase IV clinical trial titled "A Phase IV, Multicenter, Open-Label, Single Arm Study to Evaluate Safety and Efficacy of Nivorz® Administered Intravenously for its Approved Indications in Indian Participants" vide Study protocol no. NU-02-001, Version 1.0 dated 03 JUN 2026) After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial subject to the following conditions: 1) The number of patients enrolled in the trial should be stratified to include all approved indications. 2) Sample size in the clinical trial shall be increased to 170 evaluable subjects. 3) All PIs shall be Medical Oncologist. 4) Day care facilities shall not be used as a clinical trial site. 5) Clinical trial sites shall be geographically distributed. 6) Number of patients shall be proportionate between government and private clinical trial sites. Accordingly revised protocol shall be submitted to CDSCO for further evaluation.
5.	E-Receipt No.: 162318 Sacituzumab Vedotin	M/s. Zydus LifeSciences Limited	The firm presented the protocol amendment for introduction of an intermediate 0.6mg/kg dose level in the ongoing Phase I/II clinical trial of Sacituzumab vedotin approved vide Protocol No. SACI.25.001, Version 2 dated 14.10.2025. Further, the firm also presented DSMB report on monitoring of adverse events and patient safety along with the rationale of dose introduction in the clinical trial. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
6.	E-164310 Pembrolizumab Injection 100 mg/4 mL (25 mg/ML)	M/s. Sun Pharmaceutical Industries Limited	The firm presented the amendment in the protocol of Phase III clinical trial of Pembrolizumab Injection 100 mg/4 mL (25 mg/mL) in a single vial vide Protocol No. ICR/25/012, Version No. 3.0 dated 9th June

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			2026. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
7.	BIO/CT04/FF/2026/57589 Talquetamab solution for injection 3mg (2mg/ml) & 40mg (40mg/ml)	M/s. Johnson and Johnson	The firm presented the Phase IV CT protocol for Talquetamab solution for injection 3mg (2mg/ml) & 40mg (40mg/ml); Protocol - 64407564MMY4008; Phase 4, Version: Original After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial subject to the following conditions: 1. Sample size shall be increased to at least 120 subjects 2. Interim patient safety data to be submitted for 20 patients enrolled in government hospitals. 3. The principal investigator should be a qualified medical oncologist or haematologist (DM, DrNB or equivalent) 4. Clinical trial sites shall be geographically distributed. Accordingly, the firm shall submit interim safety data on 20 patients from government site to this office for further evaluation by this committee.
8.	BIO/CT18/FF/2026/57311 Durvalumab Solution for Infusion 120 mg/2.4 mL and 500 mg/10 mL	M/s. Astra Zeneca	The firm presented the proposal for grant of permission to import and market Durvalumab Solution for Infusion 120 mg/2.4 mL and 500 mg/10 mL based on safety and efficacy global data of POTOMAC Phase III study conducted outside India for the following additional indication- 1. Durvalumab in combination with Bacillus Calmette-Guérin (BCG) for the treatment of adult patients with BCG-naïve, high-risk non-muscle-invasive bladder cancer (NMIBC) with local Phase III clinical trial waiver. The committee noted that the proposed drug Durvalumab is approved in USA for this indication. After detailed deliberation, the committee

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			agreed that there is an unmet medical need for treatment of adult patients with BCG-naive, high-risk non-muscle-invasive bladder cancer (NMIBC) and recommended for grant of permission to import and market the drug with waiver of local Phase III clinical trial with condition to conduct Phase IV clinical trial in India. Accordingly, Phase IV clinical trial protocol should be submitted by firm within 3 months from grant of marketing authorization.