

**Recommendations of the SEC (Oncology) made in its 09<sup>th</sup>/26 meeting held on 18.03.2026 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>Biological Division</b>			
1.	<p>BIO/CT21/BO/2025/51664</p> <p>Nivolumab Injection 20mg/2mL, 40mg/4mL, 100mg/10mL, 120mg/12mL and 240mg/24mL</p>	<p>M/s. Dr. Reddys Laboratories Limited</p>	<p>The firm presented the proposal for grant of permission to manufacture and market the Drug Product Nivolumab Concentrate for solution for intravenous infusion (20mg/2mL, 40mg/4mL, 100mg/10mL, 120mg/12mL and 240mg/24mL) based on the results of Phase-I/III clinical trial (NU-01-001) conducted by the firm to establish the efficacy, safety, pharmacokinetic and immunogenicity of the drug product in locally advanced or metastatic non-small cell lung cancer (NSCLC).</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market Nivolumab 40mg/4mL, 100mg/10mL and 240mg/24mL concentrate for solution for intravenous infusion for the indication locally advanced or metastatic non-small cell lung cancer (NSCLC).</p> <p>Further firm has also presented proposal for approval of additional indications by the way of extrapolation in line with indications approved for innovator product based on prescribing information.</p> <p>After detailed deliberation, the committee recommended for approval of the applied additional indications that are already approved for innovator product in India subject to the condition that firm shall conduct Phase IV study in the country for all approved indications including locally advanced or metastatic non-small cell lung</p>

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			<p>cancer (NSCLC).</p> <p>Accordingly, the protocol to conduct the Phase IV study shall be submitted within three months of grant of marketing authorization permission to manufacture and market the product.</p>
2.	<p>BIO/CT04/FF/2025/53233</p> <p>Nivolumab + Relatlimab fixed-dose combination (FDC) 240 mg/80 mg in 20 mL concentrate for solution for infusion</p>	M/s. Bristol-Myers Squibb India Pvt. Ltd.	<p>The firm presented the proposal to conduct Phase IV clinical trial titled “A Phase 4, single arm, open label study to evaluate safety, tolerability, and efficacy of Nivolumab + relatlimab Fixed-Dose Combination (FDC) in participants with previously untreated, unresectable or metastatic melanoma in India” as per Protocol No. CA2241125 Version 1.0 dated 27.10.2025.</p> <p>After detailed deliberation, the committee recommended following changes in the presented protocol:</p> <ol style="list-style-type: none"> <li>1. The exclusion criteria shall be revised to reflect real-world clinical settings. Accordingly, the sample size shall be re-evaluated and increased.</li> <li>2. All PIs shall be Medical Oncologist.</li> <li>3. Day care facilities shall not be used as a clinical trial site.</li> <li>4. Clinical trial sites shall be geographically distributed.</li> <li>5. Post-trial access of the study drug shall be provided to the subjects until disease progression.</li> </ol> <p>Accordingly, the revised protocol shall be submitted to CDSCO for further evaluation by the committee.</p>
3.	<p>BIO/CT18/FF/2025/53120</p> <p>Mirvetuximab soravtansine</p>	M/s. AbbVie Healthcare India Private Limited	<p>The firm presented the proposal for grant of permission to import and market Mirvetuximab Soravtansine Injection 5 mg/mL, with a request for</p>

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	injection 5mg/ml		<p>waiver of local clinical trial, for the following indication, in line with the EU-SmPC:</p> <p>Mirvetuximab Soravtansine Injection 5 mg/mL as monotherapy for treatment of adult patients with folate receptor-alpha (FR) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens.</p> <p>The committee noted that the said drug product is approved in more than 40 countries including the United States, European Union, United Kingdom, Australia, Switzerland, and Canada and has a significant therapeutic advancement over the current standard care.</p> <p>After detailed deliberation, the Subject Expert Committee (SEC) recommended grant of permission to import and market Mirvetuximab Soravtansine Injection 5 mg/mL for the above-mentioned indication, subject to the following conditions:</p> <ol style="list-style-type: none"> <li>1) Approval of its companion diagnostic kit before marketing of the drug.</li> <li>2) The firm shall conduct a Phase IV clinical trial in adequate no. of Indian subjects in the proposed indication.</li> </ol> <p>Accordingly, a protocol to conduct the Phase IV study shall be submitted to CDSCO within 3 months of grant of approval for the proposed indication.</p>
4.	BIO/CT18/FF/2025/5 1864 Belantamab mafodotin powder	M/s. GlaxoSmithKline Pharmaceuticals Limited	The firm presented the proposal for grant of permission to import and market Belantamab Mafodotin powder for concentrate for solution for infusion

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	for concentrate for solution for infusion 70 mg and 100 mg		<p>70 mg and 100 mg, with a request for waiver of local clinical trial, for the following indications in line with the EU-SmPC:</p> <p>“Belantamab mafodotin is indicated in adult patients for the treatment of relapsed or refractory multiple myeloma:</p> <ul style="list-style-type: none"> <li>(i) in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy; and</li> <li>(ii) in combination with pomalidomide and dexamethasone in patients who have received at least one prior therapy including lenalidomide.”</li> </ul> <p>The committee noted that the said drug product is approved in more than 35 countries worldwide, including the European Union, United Kingdom, Japan, Canada, and Australia and has a significant therapeutic advancement over the current standard care.</p> <p>After detailed deliberation, the Subject Expert Committee (SEC) recommended grant of permission to import and market Belantamab Mafodotin powder for concentrate for solution for infusion 70 mg and 100 mg for the above-mentioned indications, subject to the condition that the firm shall conduct a Phase IV clinical trial in the Indian population in the proposed indications.</p> <p>Accordingly, a protocol to conduct the Phase IV study shall be submitted to CDSCO within 3 months of grant of approval for the proposed indications.</p>

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5.	BIO/CT04/FF/2025/5 3357  Pembrolizumab 100 mg/4 mL (25 mg/mL) solution for injection	M/s. Lupin Limited	<p>The firm presented the proposal to conduct Phase III clinical trial titled “A Prospective, Multi-center, Randomized, Double-blind, Active-control, Parallel-group Clinical Study to Compare Efficacy, Safety, Immunogenicity, and Pharmacokinetics of Lupin’s Pembrolizumab (LUBT021) versus Keytruda in Treatment of Patients with Metastatic Non-small Cell Lung Cancer (NSCLC)” As per Protocol No. LRP/LUBT021/2025/001; Version No. 10; Dated: 17th November, 2025.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as per the presented protocol, subject to the following conditions:</p> <ol style="list-style-type: none"> <li>1. ORR should be the primary endpoint.</li> <li>2. All PIs shall be Medical Oncologist.</li> <li>3. Day care facilities shall not be used as a clinical trial site</li> <li>4. Clinical trial sites shall be geographically distributed</li> <li>5. Post-trial access of the study drug shall be provided to the subjects until disease progression.</li> </ol>
6.	BIO/CT18/FF/2025/5 3344  Enfortumab Vedotin [Powder for concentrate for solution (20mg and 30mg)]	M/s. Astellas Pharma India Private Limited	<p>The firm presented the proposal for grant of approval of following additional indication of the drug Enfortumab vedotin [Powder for concentrate for solution (20mg and 30mg), in line with EU-SmPC along with a request for a local clinical trial waiver:</p> <p>Enfortumab vedotin [Powder for concentrate for solution (20mg and 30mg), in combination with</p>

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			<p>pembrolizumab, is indicated for the first-line treatment of adult patients with unresectable or metastatic urothelial cancer who are eligible for platinum-containing chemotherapy.</p> <p>The committee noted that the said drug product is approved in major countries, including United States, European Union, United Kingdom, Japan, Canada, and Australia and has a significant therapeutic advancement over the current standard care.</p> <p>After detailed deliberation, the Committee recommended grant of approval for the proposed additional indication, subject to the condition that the firm shall conduct a Phase IV clinical trial in the Indian population in the proposed indication.</p> <p>Accordingly, a protocol to conduct the Phase IV study shall be submitted to CDSCO within 3 months of grant of approval for the proposed indication.</p>
<b>New Drug Division</b>			
7.	ND/MA/25/000101 Belzutifan tablets 40 mg	M/s. Zydus Lifesciences Limited	<p>In light of earlier SEC recommendation dated 03.12.2025, firm re-deliberated their proposal for grant of permission for manufacture and marketing of the drug, Belzutifan 40 mg tablet along with justification for local Phase III Clinical Trial waiver before the committee.</p> <p>The committee noted that the drug is approved in USA and EU. The committee opined that there is an unmet medical need for the indication of Von Hippel-Lindau (VHL) associated tumours.</p> <p>Further, the committee also reviewed the justification presented by the firm regarding no ethnic variability. The</p>

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			<p>committee agreed for local Phase III CT waiver in VHL associated tumours only, however, the committee opined that firm should conduct well-structured Phase IV CT and submit interim analysis report on safety and efficacy of said drug product in Indian patients for further review by the committee.</p> <p>After detailed deliberation, the committee recommended for the grant of permission for the manufacture and marketing of the drug, Belzutifan 40 mg tablet with waiver of local Phase III clinical trial with the condition that the firm should conduct Phase IV clinical trial for which the protocol should be submitted within 3 months of approval of the drug for review by the committee.</p>
8.	ND/CT/25/000093 Relugolix Tablets 120 mg	M/s. BDR Pharmaceuticals International Pvt Ltd	<p>In compliance with the condition of permission for manufacture and market of the drug, Relugolix Tablets 120 mg, the firm presented Phase IV clinical trial protocol (Protocol no. SLS-CT-0006-24-RELU, Version No.: 03 and Date 21 Jan 26) before the committee.</p> <p>After detailed deliberation, committee recommended for grant of permission to conduct Phase IV clinical trial as per the protocol presented by the firm.</p>