

**Recommendations of the SEC (Oncology) made in its 32<sup>nd</sup>/25 meeting held on 14.10.2025 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/128/25 Online Submission (51657)  JNJ-61186372 (Amivantamab)	M/s Johnson & Johnson Pvt. Ltd.	The firm presented Phase III study Protocol No.: 61186372HNC3001 version no. Original dated 23-JUL-2025.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the firm shall increase the number of subjects in India.
<b>Biological Division</b>			
2.	BIO/CT04/FF/2025/50106  Pertuzumab + Trastuzumab Solution for Injection (600 mg + 600 mg)/10 mL Vial	M/s Intas Pharmaceuticals Limited	The firm presented the proposal for grant of permission to conduct Phase I clinical trial titled "A randomized, double-blind, three-arm, balanced, single-dose, Phase I, Parallel-group study to compare the pharmacokinetics of INTP78 (Pertuzumab 600 mg, Trastuzumab 600 mg) (test product-T) of Intas Pharmaceuticals Limited, India with the EU-licensed Phesgo (reference product-R1) and US-licensed Phesgo (reference product- R2) in normal, healthy, adult, human male subjects"; vide Protocol Number: 0024-25, Version: 1.0 and Date:15-May-2025 for export purpose.  After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I clinical trial as per the protocol presented by the firm, subject to the following conditions:  1. The firm shall constitute independent centralized Data & Safety Monitoring Board (DSMB) to monitor the proposed study. 2. A consolidated report of SAEs in first 100 subjects (cumulative) shall be presented before the committee.
3.	BIO/CT18/FF/2025/50168  Ipilimumab (Brand name:	M/s Bristol-Myers Squibb India Pvt. Ltd	The firm presented a proposal for grant of approval of following additional

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	Yervoi®) 5mg/mL concentrate for solution for infusion (50 mg)		<p>indications of Ipilimumab 5 mg/mL concentrate for solution for infusion (50mg/10mL).</p> <ul style="list-style-type: none"> <li>• <b>Hepatocellular Carcinoma:-</b> Ipilimumab, in combination with nivolumab, is indicated for the first-line treatment of adult patients with unresectable or metastatic hepatocellular carcinoma (HCC).</li> <li>• <b>Melanoma:-</b> Ipilimumab in combination with Nivolumab is indicated for the treatment of unresectable or metastatic melanoma in adult patients.</li> </ul> <p>The committee noted that the proposed indication w.r.t Hepatocellular Carcinoma is approved in 43 countries including US, EU, UK, Canada, Japan, Australia and Switzerland. Similarly the proposed indication w.r.t Melanoma is approved in 76 countries including United States, EU, Australia, Canada, Japan and Switzerland.</p> <p>After detailed deliberation, the committee recommended for grant of approval for the proposed additional indications.</p>
4.	BIO/CT04/FF/2025/50397  Sintilimab Injection 100 mg/10 ml (per vial) (Intravenous Infusion)	M/s Mankind Pharma Ltd.	<p>The firm presented a proposal to conduct a clinical trial titled, “A Phase III, Randomized, Open label, Parallel Group, Multi-centre Study to Assess the Efficacy and Safety of Sintilimab plus Chemotherapy compared to Chemotherapy alone as First-Line Treatment for Patients with Locally Advanced or Metastatic Non-Squamous Non-Small Cell Lung Cancer (NSCLC) vide protocol no. MPL-SIN-001 version 1.1 dated 14.08.2025. The firm has presented the PK/PD and Phase-III data, primarily generated on Chinese population. The committee noted that</p>

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			<p>Sintilimab Injection is approved in China only. Safety in Indian Population has not been adequately addressed either by available data or provision in the present study design. It was also observed that comparator arm (chemotherapy) is inferior when indicated therapy is available in India.</p> <p>After detailed deliberation, committee recommended that firm should first conduct Phase-I study in the Indian population.</p> <p>Accordingly, firm is required to submit the Phase-I protocol to the CDSCO.</p>
5.	<p>BIO/CT18/FF/2025/50150</p> <p>Nivolumab 10 mg/ml concentrate of solution for infusion (40 mg/4ml, 100 mg/10 ml and 240 mg/24 ml)</p>	<p>M/s Bristol-Myers Squibb India Pvt. Ltd</p>	<p>The firm presented a proposal for grant of approval of following additional indications of Nivolumab 10 mg/ml concentrate of solution for infusion (40 mg/4 ml, 100 mg/10 ml and 240 mg/24 ml).</p> <ul style="list-style-type: none"> <li>• <b>Hepatocellular Carcinoma:-</b> Nivolumab, in combination with ipilimumab, is indicated for the first-line treatment of adult patients with unresectable or metastatic hepatocellular carcinoma (HCC).</li> <li>• <b>Melanoma:-</b> Nivolumab, in combination with ipilimumab, is indicated for the treatment of patients with unresectable or metastatic melanoma.</li> </ul> <p>The committee noted that the proposed indication w.r.t Hepatocellular Carcinoma is approved in 43 countries including US, EU, UK, Canada, Japan, Australia and Switzerland. Similarly the proposed indication w.r.t Melanoma is approved in 76 countries including United States, EU, Australia, Canada, Japan and Switzerland.</p>

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			After detailed deliberation, the committee recommended for grant of approval for the proposed additional indications.
6.	BIO/CT18/FF/2025/50241  Nivolumab 10 mg/ml concentrate for solution for infusion (40 mg/4ml, 100 mg/10 ml, 240 mg/24ml)	M/s Bristol-Myers Squibb India Pvt. Ltd.	<p>The firm presented a proposal for grant of approval of following additional indications of Nivolumab 10 mg/ml concentrate of solution for infusion (40 mg/4ml, 100 mg/10 ml and 240mg/24ml).</p> <ul style="list-style-type: none"> <li>• <b>Colorectal Cancer (CRC):</b> Nivolumab, in combination with ipilimumab, is indicated for the treatment of adult and pediatric patients 12 years and older with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (CRC).</li> <li>• <b>Malignant Pleural Mesothelioma:</b> Nivolumab, in combination with ipilimumab, is indicated for the first-line treatment of adult patients with unresectable malignant pleural mesothelioma.</li> </ul> <p>The committee noted that the proposed indication w.r.t Colorectal cancer is approved in 42 countries including US, EU, UK, Canada, Japan, Australia and Switzerland. Similarly the proposed indication w.r.t Malignant Pleural Mesothelioma is approved in 80 countries including US, EU, Canada, Japan, Australia and Switzerland.</p> <p>After detailed deliberation, the committee recommended for grant of approval for the proposed additional indications.</p>
7.	BIO/CT18/FF/2025/50262	M/s Bristol-Myers Squibb India Pvt.	The firm presented a proposal for grant of approval of following additional

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	Ipilimumab 5 mg/mL concentrate for solution for infusion (50 mg/10 mL)	Ltd	<p>indications of Ipilimumab 5 mg/mL concentrate for solution for infusion (50 mg/10 mL).</p> <ul style="list-style-type: none"> <li>• <b>Colorectal Cancer (CRC):</b> Ipilimumab, in combination with nivolumab, is indicated for the treatment of adult and pediatric patients 12 years and older with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (CRC).</li> <li>• <b>Malignant Pleural Mesothelioma:</b> Ipilimumab, in combination with nivolumab, is indicated for the first-line treatment of adult patients with unresectable malignant pleural mesothelioma.</li> </ul> <p>The committee noted that the proposed indication w.r.t Colorectal cancer is approved in 42 countries including US, EU, UK, Canada, Japan, Australia and Switzerland. Similarly the proposed indication w.r.t Malignant Pleural Mesothelioma is approved in 80 countries including US, EU, Canada, Japan, Australia and Switzerland.</p> <p>After detailed deliberation, the committee recommended for grant of approval for the proposed additional indications.</p>
<b>New Drugs Division</b>			
8.	ND/IMP/25/000068 Fruquintinib 1 mg and 5 mg Hard capsule	M/s. Takeda Biopharmaceuticals India Pvt. Ltd	<p>The firm presented the proposal for grant of permission for import and marketing of the drug Fruquintinib Capsules 1 mg and 5 mg along with justification for local Phase III Clinical Trial waiver before the committee.</p> <p>The committee reviewed two Phase III clinical trial data submitted by the firm conducted in other countries.</p> <p>After detailed deliberation, committee opined that the firm should provide a</p>

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			<p>comprehensive presentation substantiating the claim w.r.t. no ethnic variability in Indian population and addressing the safety profile of the drug. Further, the committee recommended that firm should conduct well-structured Phase IV clinical trial in Indian patients to evaluate the safety concerns with the molecule. In this regard, firm should submit Phase IV CT protocol to CDSCO for further review by the committee.</p>
<b>SND Division</b>			
9.	<p>SND/CT/25/00055</p> <p>Amlodipine tablets 10 mg (Additional indication)</p>	<p>M/s Raptim Research Pvt. Ltd</p>	<p>In light of earlier SEC recommendation dated 23.09.2025, the firm Presented Phase II study protocol of Amlodipine Tablets 10 mg along with the proof of concept retrospective data/ literature before the Committee.</p> <p>The Committee noted that the submitted data is not adequate to support the proposed Study protocol and Proof of concept needs to be established.</p> <p>Therefore, the committee opined that firm should revise the protocol as Proof of concept study with appropriate study design, sample size (considering age, disease condition etc) with clearly defined endpoints.</p> <p>Accordingly, the firm should submit revised protocol for deliberation before the committee.</p>