

Recommendations of the SEC (Oncology) made in its 25th/25 meeting held on 06.08.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/145/23 Online Submission (39985) Volrustomig (MEDI5752)	M/s AstraZeneca Pharma India Limited	The firm presented protocol amendment version 3.0 dated 13 May 2025 protocol no. D798EC00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/110/21 Online Submission (40117) ABL001 (Asciminib)	M/s Novartis Healthcare Private Limited	The firm presented protocol amendment version 04 dated 05 May 2025 protocol no. CABL001J12301. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/35/23 Online Submission (40168) Mezigdomide, CC-92480 (BMS-986348)	M/s Bristol-Myers Squibb India Pvt. Ltd.	The firm presented protocol amendment 04 dated 11 Feb 2025 protocol no. CA057008. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
4.	BIO/CT18/FF/2025/48 513 Nivolumab (Opdyta®) 10 mg/mL concentrate for solution for infusion: 40 mg, 100 mg and 240 mg	M/s Bristol-Myers Squibb India Pvt. Ltd.	The firm presented the proposal for approval of additional indication of Nivolumab (Opdyta®) 10 mg/ mL concentrate for solution for infusion: 40 mg, 100 mg and 240 mg i. e “Nivolumab, in combination with platinum-doublet chemotherapy, is indicated for the neoadjuvant treatment of adult patients with resectable (tumors \geq 4 cm or node positive) NSCLC and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements, followed by single-agent Nivolumab as adjuvant treatment after surgery” based on the results of global clinical studies conducted by the firm along with a request for waiver for local clinical trial. The committee noted that the proposed indication is approved in countries including USA, Australia, and UK. The committee further noted that a Phase IV

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			<p>study in India in NSCLC is completed and there is adequate safety and efficacy data available in Indian population.</p> <p>After detailed deliberation, the committee recommended for the approval of proposed additional indication in line with USFDA approved indication subject to condition that firm should conduct a Post marketing surveillance in India for the proposed approved indication. Accordingly, the firm should submit PMS protocol to CDSCO within three months of approval of additional indication.</p>
BA/BE Division			
5.	<p>BABE/CT05/FF/2025/50031</p> <p>Degarelix Extended-Release Injection, 371 mg/mL</p>	<p>M/s. CBCC Global Research LLP</p>	<p>The firm presented the Study Protocol No.TOL3022A-101, Version No. 01, Protocol Date- 02-05-2025 for export purpose only.</p> <p>After detailed deliberation, the committee opined that the firm shall submit the revised protocol with respect to following for further review by the committee:</p> <ol style="list-style-type: none"> 1. To include an Inclusion criterion for Hemoglobin levels at the Screening Stage. 2. Include provisions of Post Trail Access of the study drug as per NDCT Rules 2019.
SND Division			
6.	<p>SND/IMP/25/000036</p> <p>Ribociclib film-coated tablets 200 mg</p>	<p>M/s Sandoz Private Limited</p>	<p>Firm presented proposal for grant of permission to Import and marketing of Ribociclib film coated tablets 200 mg for the treatment of early breast cancer with waiver of Phase-III and Phase IV clinical trial.</p> <p>Firm has informed that, they had received permission to conduct the Global Phase IIIb Clinical Trial on 23/07/2025 for the indication of treatment of early breast cancer which is ongoing.</p> <p>After detailed deliberation, the committee recommended that firm should submit report of ongoing Global Phase IIIb</p>

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			Clinical Trial at planned time points in approved protocol before the committee for further consideration
7.	SND/IMP/25/000053 Darolutamide Film Coated Tablets 300 mg	M/s. Bayer Pharmaceuticals Pvt. Ltd.	<p>Firm presented their proposal for grant of permission to manufacture and marketing of Darolutamide Film Coated Tablets 300 mg for the treatment of patients with metastatic hormone sensitive prostate cancer (mHSPC).</p> <p>The firm has informed that they have already received approval for the proposed indication in USA, U.K and Europe.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Darolutamide Film Coated Tablets 300 mg for the proposed indication subject to condition that the firm should conduct Active PMS Study in at least 200 patients.</p> <p>Accordingly, the firm should submit Active PMS Study protocol to CDSCO within three months from date of approval of the drug.</p>
New Drugs Division			
8.	ND/IMP/25/000049 Olutasidenib Capsules 150 mg	M/s Dr Reddy's Laboratories Limited	<p>The firm presented the proposal for grant of permission for Import and Marketing of the drug Olutasidenib Capsules 150 mg indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation along with justification for local Phase III Clinical Trial waiver before the committee.</p> <p>The presented the global clinical data for safety and efficacy of the drug.</p> <p>The committee noted that the drug is approved in US and Europe. There is unmet medical need in the country.</p> <p>After detailed deliberation, the committee recommended for the grant of permission</p>

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			<p>for the import and marketing of the drug Olutasidenib Capsules 150 mg with waiver of Phase III clinical trial with 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> <p>The Committee noted that differentiation syndrome should be specifically mentioned as side-effect of special interest in Prescribing Information and accordingly, firm should submit revised prescribing information to CDSCO highlighting the said warning.</p>