

**Recommendations of the SEC (Oncology) made in its 9<sup>th</sup>/24 meeting held on 02.05.2024 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/47/24 Online Submission (42604)  AZD0901 Powder for Solution for infusion	M/s. AstraZeneca	The firm presented Phase III clinical study protocol No. D9802C00001, version 1.0 dated 13 Oct 2023, clinical study protocol-addendum IND-1 version 1.0 dated 20 Feb 2023.  After detailed deliberation, the committee recommended that the firm should submit complete safety data from Phase-II clinical study for further review by the committee.
2.	CT/48/24 Online Submission (42691)  MK-2870	M/s. MSD	The firm presented Phase III clinical study protocol No. MK-2870-009 Version No. 00 dated 24-Jan-2024.  After detailed deliberation, the committee recommended that the firm should submit complete safety data along with detailed SAE's reported during the Phase-II study for further review by the committee.
3.	CT/50/24 Online Submission (42642)  Ribociclib	M/s. Novartis	The firm did not turn up for presentation.
4.	CT/53/24 Online Submission (42731)  FYB206 (Pembrolizumab)	M/s. Inventiv	The firm presented Phase III clinical study protocol No. FYB206-C3-02, version 2.0 dated 22 February 2024.  After detailed deliberation, the committee recommended that the firm should submit preclinical study data for further review by the committee and selection of government and private sites should be done in a balanced manner in the study.
<b>SND Division</b>			
5.	SND/CT/24/000008  Cyclophosphamide Powder for Oral Solution 30mg/ml (600mg/20ml)	M/s. Intas Pharmaceuticals Limited	The firm presented the proposal for grant of permission to conduct palatability study of Cyclophosphamide powder for oral solution 30mg/ml (600mg/20ml) for export purpose along with palatability study protocol (protocol No.: 72189805, version No.: 5.0 Dated 25.05.2023)

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			<p>before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct palatability study as per protocol presented by the firm.</p>
6.	<p>SND/IMP/23/000071</p> <p>Osimertinib Tablets 40mg &amp; 80mg (TAGRISSO)</p>	<p>M/s. Astra Zeneca Pharma India Limited</p>	<p>In light of earlier SEC recommendations dated 07.02.2024 &amp; 08.02.2024, the firm presented additional scientific rationale and clinical safety data before the committee.</p> <p>The firm has informed that the proposed indication is already approved in the USA, Switzerland, South Korea, Russia, New Zealand and Brazil. The firm submitted more clinical data of FLAURA-2 trial wherein India is one of the participating country.</p> <p>After detailed deliberation, the committee recommended for grant of proposed additional indication.</p>