

**Recommendations of the SEC (Oncology & Haematology) made in its 143<sup>rd</sup> meeting held on 23.02.2023 at CDSCO (HQ), New Delhi:**

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>New Drugs Division</b>			
1.	ND/IMP/22/000004  Entrectinib 100mg and 200mg capsules	M/s. Roche	<p>In light of earlier recommendation of SEC dated 09.12.2022 the firm presented its alternative proposal for Phase IV clinical trial study for drug Entrectinib 100 and 200mg capsules before the committee.</p> <p>After detailed deliberation, the committee recommended that:</p> <ol style="list-style-type: none"> <li>1. The firm should officially submit a proposal for deliberation of both molecules: Entrectinib &amp; Pralsetinib.</li> <li>2. Considering the rarity of indications in which the molecules are approved, and the fact that they are approved only in a molecularly identified small subset of patients, the basket trial design submitted is acceptable.</li> <li>3. However, the committee did not accept the proposal of the company wanting to do just collection of real world evidence. The company should officially submit a proposal to do a Phase IV trial, wherein there is structured collection of data &amp; wherein patients will get the molecules free until they continue to respond or there is unacceptable toxicity.</li> <li>4. Considering the rarity of approved indications, the company's request to do the Phase IV basket trial in 40 evaluable patients is acceptable.</li> </ol>
<b>Biological Division</b>			
2.	BIO/CT/22/000120  Trastuzumab 150 mg and 440mg in vial	M/s. Hetero Biopharma Limited	The firm presented the proposal for conduct of Phase IV clinical trial titled "A Phase IV multi-centric, post-marketing study evaluating the safety, immunogenicity and efficacy of the marketed formulation of Hetero-Trastuzumab in Female Patients with HER2+ Breast Cancer" vide protocol no

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
			HCR/IV/TRUMAB/05/2022 version 1.0 dated 14 May 2022.  After detailed deliberation, the committee recommended for approval of the Phase IV study as presented by the firm.
3.	BIO/CT/04/FF/2022/3 3964  Pertuzumab 420 mg/14ml vial	M/s. Enzene Biosciences Limited	The firm presented the protocol for conduct of Phase III clinical trial titled “prospective, randomized, multicenter, comparative, double-blind, parallel study to evaluate the efficacy, safety, pharmacokinetics, and Immunogenicity of biosimilar Pertuzumab (ENZENE) with reference Pertuzumab(Perjeta®, Genentech Inc.) in previously untreated patients with HER2 Positive Metastatic Breast Cancer” vide protocol ALK28/ENZ130-PER1 version 1.0 dated 25.07.2022.  After detailed deliberation, the committee recommended for grant of permission to conduct the subject study as presented by the firm.
4.	46/Phase IV/GSK/13-BD (Part-I)  Panitumumab 100 mg vial (20 mg/ml)	M/s. Dr. Reddy’s Lab	The firm presented the results of Phase IV clinical trial conducted in India.  After detailed deliberation, the committee noted the results of the study.
5.	BIO/CT/18/FF/2022/3 4831  Dostarlimab	M/s. GSK	The firm presented the proposal to import and marketing of the drug Dostarlimab concentrate for solution for infusion 500 mg/10 ml indicated as monotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-containing regimen with local clinical trial waiver. The firm presented the results of various clinical trials conducted in other countries.  The committee noted that the drug is approved in around 40countries including US, European Union, United Kingdom, Canada, Australia, Switzerland, etc.  The committee opined that the drug is

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
			<p>falling under the category of orphan drug and indicated for the treatment of life threatening disease and there is an unmet medical need in the country.</p> <p>After detailed deliberation, the committee recommended for grant of permission to import and market the drug with waiver of Phase III clinical trial in the country with the condition that the firm should conduct Phase IV clinical trial. Accordingly, Phase IV clinical trial protocol should be submitted within 3 months of import and marketing permission granted.</p>
6.	<p>BIO/CT18/FF/2022/3 3163</p> <p>Trastuzumabderuxtec an Concentrate Solution for infusion 100 mg</p>	M/s. Astra Zeneca	<p>In light of earlier SEC recommendation dated 11.11.2022, the firm presented the current status of the ongoing clinical trial of Trastuzumab Deruxtec Powder for Concentrate for Solution for Infusion 100mg for import and marketing in India. The drug is indicated for treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received one or more prior anti-HER2- based regimens with local Phase III clinical trial waiver.</p> <p>The committee noted that the drug is approved in Japan, US, EU, UK, Israel, Canada, Switzerland, Australia, Singapore, Brazil, Taiwan, Hongkong, UAE, South Korea.</p> <p>The committee opined that the drug is indicated for the treatment of life threatening disease and there is an unmet medical need in the country.</p> <p>After detailed deliberation, the committee recommended for grant of permission to import and market the drug with waiver of Phase III clinical trial in the country with the condition that the firm should conduct Phase IV trial in minimum 150 subjects. Accordingly, Phase IV clinical trial protocol should be submitted within 3 months of import and marketing permission granted.</p>
7.	BIO/CT18/FF/2022/3 4766	M/s. Roche Products (I) Pvt. Ltd.	The firm presented the proposal for import & marketing of the drug Polatuzumab Vedotin for Injection,

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Polatuzumab Vedotin for Injection 30 mg/vial & 140 mg/vial		<p>30mg/vial and 140 mg/vial. The drug in combination with Rituximab, Cyclophosphamide, Doxorubicin, and Prednisone (R-CHP) is indicated for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma (DLBCL) with local Phase III clinical trial waiver.</p> <p>The committee noted that the drug is approved in EU, UK, Canada, Japan, China, Singapore and Australia.</p> <p>The committee noted that global clinical trials are ongoing in which India is also part of the trials.</p> <p>The committee noted that the drug is falling under the category of orphan drug and indicated for the treatment of life threatening disease and there is an unmet medical need in the country.</p> <p>After detailed deliberation, the committee recommended for grant of permission to import and market the drug with waiver of Phase III clinical trial in the country with the condition that the firm should conduct Phase IV trial. Accordingly, Phase IV clinical trial protocol should be submitted within 3 months of import and marketing permission granted.</p>
8.	BIO/MA/22/000104  Denosumab 60 mg injection	M/s. Enzene Bioscience Limited	<p>In light of earlier SEC recommendation dated 10.01.2023, the firm presented the proposal along with justification for extrapolation for approval of proposed additional indications before the committee.</p> <ol style="list-style-type: none"> <li>1. Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer.</li> <li>2. Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.</li> </ol> <p>After detailed deliberation, the committee recommended for approval of proposed additional indications with</p>

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
			condition that firm should submit safety data of the drug for the proposed indication after one year for further review by the committee.
<b>SND Division</b>			
9.	SND/IMP/22/000088  Olaparib Film coated Tablet 100/150 mg	M/s. AstraZeneca Pharma	<p>The firm presented the proposal for import &amp; marketing of the drug Olaparib film-coated Tablets 100mg/150mg for additional indication as <b>“In Combination with Abiraterone and Prednisone or Prednisolone is indicated for the treatment of adult patients with metastatic castration-resistant prostate cancer”</b> along with CT waiver justification and some global clinical trial data, before the committee.</p> <p>The committee noted that the firm was shown Phase IV/ PMS data in Indian patient for the drug product and presented some Global clinical trial data of Olaparib conducted in other countries with respect to proposed indication. The committee also noted that India was not part of these global clinical trials.</p> <p>In view above, the committee recommended that the firm should conduct Phase III clinical trial for the proposed indication. The firm should submit Phase III clinical trial protocol for further review by the committee.</p>
<b>GCT Division</b>			
10.	CT/141/22 Online Submission (34825)  Ianalumab(VAY736)	M/s. Novartis	The proposal was deferred for next meeting.
11.	CT/84/20 Online Submission (21202)  Durvalumab	M/s. AstraZeneca	The proposal was deferred for next meeting.
12.	CT/42/22 Online Submission (21910)  Durvalumab+Olaparib	M/s. Labcorp	The proposal was deferred for next meeting.
13.	CT/143/22 Online Submission (34837)  Ianalumab	M/s. Novartis	The proposal was deferred for next meeting.

<b>S.No</b>	<b>File Name &amp; Drug Name, Strength</b>	<b>Firm Name</b>	<b>Recommendations</b>
14.	CT/32/22 Online Submission (22548) Durvalumab+Olaparib	M/s. Labcorp	The proposal was deferred for next meeting.
15.	CT/41/22 Online Submission (23175) Paclitaxel-Carboplatin Oregovomab	M/s. Raptim Research	The firm did not turn up for the presentation.
16.	CT/154/22 Online Submission (34879) ASP-1929 Cetuximabsarotalocan sodium	M/s. Rakuten Medical	The proposal was deferred for next meeting.