

Recommendations of the SEC (Oncology & Haematology) made in its 148th meeting held on 11.05.2023 at CDSCO (HQ) New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/IMP/22/000082 Nivolumab 10 mg/ml concentrate for solution for infusion (40 mg & 100 mg)	M/s. Bristol-Myers Squibb India Pvt. Ltd.	The firm did not turn up for presentation.
2.	BIO/CT18/FF/2023/35862 Pembrolizumab Injection 100mg/4ml (25mg/ml) Solution for infusion	M/s. MSD Pharmaceuticals	<p>The firm presented the proposal for approval of additional indications (Renal Cell Carcinoma and Triple Negative Breast Cancer) of Pembrolizumab Injection (Keytruda) 100mg/4ml (25mg/ml solution in a single vial) with local clinical trial waiver under the category of life threatening or serious diseases and unmet need in India.</p> <p>The firm presented the clinical data of ongoing Phase IV studies in India (KEYNOTE-593) and data from ongoing global clinical trial studies for proposed indications (KEYNOTE-426, KEYNOTE-564, KEYNOTE-355 and KEYNOTE-522). The proposed indications are approved in key countries like USA, UK and Japan.</p> <p>After detailed deliberation and based on the global clinical trial data, the committee recommended for grant of permission to Pembrolizumab injection (25mg/ml) for following additional indications with local clinical trial waiver</p> <ol style="list-style-type: none"> 1. Pembrolizumab, in combination with Axitinib, is indicated for the first-line treatment of advanced renal cell carcinoma in adults 2. Pembrolizumab, as monotherapy, is indicated for the adjuvant treatment of adults with renal cell carcinoma at increased risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions. 3. Pembrolizumab, in combination with chemotherapy, is indicated for the treatment of locally recurrent unresectable or metastatic triple-negative breast cancer in adults whose tumours express PD-L1 with a CPS \geq 10 and who

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			<p>have not received prior chemotherapy for metastatic disease.</p> <p>4. Pembrolizumab, in combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery, is indicated for the treatment of adults with locally advanced, or early-stage triple-negative breast cancer at high risk of recurrence.</p>
SND Division			
3.	SND/IMP/20/000072 Osimertinib film coated tablet 40mg & 80mg	M/s. AstraZeneca	<p>The firm presented the proposal for approval of updated package insert of Osimertinib film coated tablet 40mg & 80mg before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of approval of proposed updated package insert of Osimertinib film coated tablet 40mg & 80mg.</p>
4.	SND/MA/21/000506 Lenalidomide Capsules 25 mg	M/s. Dr. Reddy's Laboratories Limited	<p>The firm presented the proposal for manufacturing and marketing permission of Lenalidomide Capsule 25mg (using Lenalidomide povidone premix) along with the results of the BE study before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Lenalidomide capsule 25mg (using Lenalidomide povidone premix) for the proposed indication as under:</p> <p>“For the treatment of patients with transfusion dependent anaemia due to low or intermediate-1-risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities and in combination with Dexamethasone for the treatment of multiple myeloma patients who have received at least one prior therapy”.</p>
FDC Division			
5.	FDC/MA/22/000258	M/s. Murli Krishna Pharma Pvt. Ltd.	In light of the earlier SEC recommendation dated 09.02.2023, the firm presented the PK study protocol for

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	Ferrous BisGlycinate +Vitamin B12 +Vitamin D3 + Folic acid (10mg+0.8mcg+20mcg+100mcg)		preclinical study. After detailed deliberation, the committee recommended that firm should present the preclinical study data along with Phase III clinical trial study protocol for review by the SEC.
GCT Division			
6.	CT/44/21 Online Submission (23581) Atezolizumab	M/s. Roche	The firm presented the proposal for protocol amendment 3.0 dated 23-Feb-2022 before the committee. After detailed deliberation, the committee recommended for grant of approval for the proposed protocol amendment.
7.	CT/124/22 Online Submission (34341) ABL001 (Asciminib)	M/s. Novartis	In light of earlier SEC recommendation dated 10.01.2023, the firm presented their justification for conduct of clinical trial Phase IIIb where the primary objective of the study is safety and also submitted regulatory approval from Germany & France for protocol number :CABL001J12302 Version 00 (Original protocol dated 24-May-22) before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the phase IIIb clinical trial as presented by the firm.
8.	CT/97/21 Online Submission (22605) Amivantamab + Lazertinib	M/s. J&J	The firm presented the proposal for protocol amendment 5, dated 22-Aug 2022 before the committee. After detailed deliberation, the committee recommended for approval for increasing the number of patients from 30 to 50.
9.	CT/23/21 Online Submission (20045) Trastuzumab Deruxtecan (T-DXd)	M/s. Astrazeneca	The firm presented the proposal for protocol version 3.0 dated 18-July-2022 before the committee. After detailed deliberation, the committee recommended for grant of approval of the proposed protocol amendment.
10.	CT/95/19 Online Submission (18331) Selpercatinib	M/s. Eli Lilly	The proposal was deferred for next SEC meeting.
11.	CT/151/22 Online Submission	M/s. Prorelix Service	In light of earlier SEC recommendation dated 11.04.2023. the firm presented their

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	(34938) KRC-01		<p>justification for the data for number of subjects (60) in Phase II, rationale for Phase I, FIGO stage III locally advanced cervical cancer, dose volume of study and regulatory approval for study protocol number (KRC-01-C01, original protocol: version 1.0 Nov2, 2022) of Phase I/II clinical study before the committee.</p> <p>The committee noted that there was no submission and approval from the participating ICH regulatory countries for the proposed Phase I/II trial. KRC-01 dose justification and safety data is not found established and the presented extrapolated data from breast cancer was not found satisfactory for the proposed indication.</p> <p>After detailed deliberation, the committee did not recommend for conduct of the study as no dose of IP (KRC-01) was established for the proposed indication in ICH countries.</p>
12.	CT/15/19 Online Submission (22767) Fitusiran	M/s. PPD	<p>The firm presented the proposal for protocol amendment 05 dated 12-Oct-2022 before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of approval of the proposed protocol amendment.</p>
13.	CT/104/21 Online Submission (22800) LY3484356	M/s. Eli Lilly	The proposal was deferred for next SEC meeting.
14.	CT/75/21 Online Submission (23014) Marstacimab Prophylaxis	M/s. Pfizer	The proposal was deferred for next SEC meeting.
15.	CT/11/23 Online Submission (35893) TAR-200 + Cetrelimab	M/s. J&J	The proposal was deferred for next SEC meeting.

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16.	CT/19/23 Online Submission (36477) Gedatolisib Powder for Solution for infusion	M/s. PSI CRO	The proposal was deferred for next SEC meeting.
17.	CT/79/22 Online Submission (25026) BCD-217 (Nurulimab +Prolgolimab)	M/s. IR Innovate Research	The proposal was deferred for next SEC meeting.
18.	CT/39/22 Online Submission (25389) JDQ443	M/s. Novartis	The proposal was deferred for next SEC meeting.
Medical Device Division			
19.	CI/MD/2022/77493 Cervical Cancer Screening Device (CerviScan)	M/s. Sascan Meditech Pvt. Ltd	<p>The firm presented the proposal for pilot clinical investigation of the proposed product Cervical Cancer screening device (CerviScan) in the country before the committee.</p> <p>After detailed deliberation, the committee recommended that sample size of the clinical investigation protocol should be statistically validated for establishing performance of the device.</p> <p>Accordingly, the firm should submit revised clinical investigation protocol to CDSCO for further review by the committee.</p>
20.	CI/MD/2023/86807 Hydrating oral Patch	M/s. Bylin Meditech Pvt. Ltd.	<p>The firm presented the proposal for pivotal clinical investigation of the proposed product hydrating oral patch in the country before the committee.</p> <p>Committee observed that sample size of clinical investigation protocol is not adequate to establish safety, efficacy and performance of the product.</p> <p>After detailed deliberation, the committee recommended that sample size of clinical</p>

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			<p>investigation protocol should be statistically validated and should not be less than 100 patients for establishing of safety, efficacy & performance of the device.</p> <p>Accordingly, the firm should submit revised clinical investigation protocol to CDSCO for further review by the committee.</p>