

Recommendations of the SEC (Oncology & Haematology) made in its 136th meeting held on 11.11.2022 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/21/000040 Pralsetinib Capsules 100mg	M/s. Roche	The firm did not turn up for presentation.
Biological Division			
2.	BIO/CT18/FF/2022/33163 Trastuzumab deruxtecan concentrate solution for infusion 100mg	M/s. Astra Zeneca	<p>The firm presented the proposal for import & marketing of the drug Trastuzumab Deruxtecan Powder for Concentrate for Solution for Infusion 100mg 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 product is approved in Japan, US, EU, UK, Israel, Canada, Switzerland, Australia, Singapore, Brazil, Taiwan, Hongkong, UAE, South Korea.</p> <p>The firm has presented the results of various clinical trials conducted in other countries.</p> <p>The committee noted that five global clinical trials are ongoing and India is also part of the trials; 70 patients have been enrolled upto, out of 200 patients (approx.) planned from India, for which clinical data are not available at present.</p> <p>After detailed deliberation, the committee recommended that the firm should submit data in Indian population from the ongoing clinical studies for further deliberation.</p>
3.	BIO/CT18/FF/2022/34303 Pembrolizumab Injection 100mg/4ml	M/s. MSD	<p>The firm presented the proposal for approval of additional indications along with results of clinical trial conducted globally and safety data of ongoing Phase IV trial in India for the following indications with local clinical trial waiver.</p> <p>1) Cervical Cancer: “Pembrolizumab, in combination with chemotherapy with or without</p>

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			<p>Bevacizumab, is indicated for the treatment of persistent, recurrent, or metastatic cervical cancer in adults whose tumours express PD-L1 with a CPS \geq 1”.</p> <p>2) Esophageal Cancer: Pembrolizumab, in combination with platinum and Fluoropyrimidine-based chemotherapy, is indicated for the first-line treatment of locally advanced unresectable or metastatic carcinoma of the esophagus or HER-2 negative gastroesophageal junction adenocarcinoma, in adults whose tumours express PD-L1 with a CPS \geq 10.</p> <p>The committee noted that the post marketing data from India are consistent with the global established safety profile. Cervical cancer and Esophageal cancer are serious or life-threatening disease and the indications are already approved in countries such as USA, EU, Canada, Japan.</p> <p>After detailed deliberation, the committee recommended for approval of proposed additional indications i.e., cervical cancer and esophageal cancer.</p>
4.	F.No.89/Phase IV/Biocon/17-BD (Pt-I) Bevacizumab	M/s. Biocon	<p>The firm presented clinical study report of Phase IV.</p> <p>After detailed deliberation, the committee noted the results of the study.</p>
5.	4-25/Roche/PAC-R-Atezolizumab/2022-BD Atezolizumab Injection 1200mg/20ml and 840mg/14ml Vials	M/s. Roche Products India Pvt. Ltd.	<p>In light of the recommendation of SEC (Gastroenterology & Hepatology) dated 18.10.2022, the firm presented proposal for amendment in warning statement from “Warning: To be sold by retail on the prescription of a Registered Oncologist only” to “Warning: To be sold by retail on the prescription of a Registered Oncologist, Gastroenterologist or Hepatologist only”.</p> <p>The committee noted that, the SEC (Gastroenterology & Hepatology) dated 18.10.2022 has already recommended for proposed amendment in warning statement and accepted the</p>

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			recommendation of the SEC (Gastroenterology & Hepatology) dated 18.10.2022.
6.	BIO/CT04/FF/2022/31049 Filgrastim biosimilar (GRANFILL) (300 mcg/ 0.5 ml)	M/s. Samarth Life Sciences Pvt. Ltd	The firm presented proposal for conduct of PK-PD study titled “An open-label, randomized, multiple dose, two periods, cross-over design to assess pharmacokinetic (PK) and pharmacodynamic (PD) equivalence of GRANFILL® (Filgrastim injection IP 300mcg/0.5ml) manufactured by: Samarth Life Sciences Pvt. Ltd., in comparison with NEUPOGEN® (Filgrastim) injection (300 mcg/0.5 mL), Manufactured by: Amgen Inc., One Amgen Center Drive, Thousand Oaks, California 91320-1799 U.S.A. in healthy adult human subjects” vide protocol SLT/CT/00122-00; Version No.: CT001-00; dated 17-AUG-2022. After detailed deliberation, the committee recommended for grant of permission to conduct the subject study as per the presented protocol.
GCT Division			
7.	CT/47/20 Online Submission (13601) Durvalumab	M/s. Astra Zeneca	The firm presented the protocol amendment version 03 dated 06-May-2022 to protocol no. D910LC00001 (MeRmaiD-1). On deliberation, the committee noted that PK/PD & ADA analysis will not be carried out as there is no further enrollment of the subjects in the trial. After detailed deliberation, the committee recommended for the approval of proposed protocol amendment to version 03 dated 06-May-2022.
8.	CT/88/22 Online Submission (33659) Ibrutinib + Rituximab	M/s. J&J	The firm presented the proposed Phase 2/3 study protocol no. 54179060MCL3004 (original version) dated 21-JUL-2022 before the committee. After detailed deliberation, the committee recommended to conduct the study with the condition that the firm should submit the part 2 study report along with IDMC report for review and approval of the SEC/CDSCO, for further continuation of the Phase 3 part of the study.

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9.	CT/37/22 Online Submission (31619) NBTX3N and CETUXIMAB	M/s. PRA	In light of earlier SEC held on 08.09.2022, the applicant has presented Phase I data which is ongoing in USA along with protocol no. NANORAY, V2.0 dated 27-Jul-2021 before the committee. The applicant mentioned that USFDA has considered a fast track development program of NBTXR3 and therefore USFDA approved proposed Phase III protocol without conduct of Phase II trial. After detailed deliberation, the committee recommended for grant of permission to conduct the study with condition that final clinical study report of Phase I to be submitted to CDSCO.
10.	CT/84/22 Online Submission (33550) Decitabine 5mg + Tetrahydrouridine 250mg	M/s. Novo- Nordisk	The proposal will be deliberated in presence of Hematology expert in forthcoming SEC.
11.	CT/78/22 Online Submission (33550) FS118	M/s. Star Genomics	The firm presented the proposed Phase 2 protocol no. FS118-21201, Version 2.0 dated 15-Mar-2022 before the committee. After detailed deliberation, the committee opined that the applicant should submit the following for further review: 1) Detailed study data as of date of Phase1/2, FS118-17101 (FIH) study along with its approval letter and further correspondence from concerned health authorities (USFDA and EU countries). 2) Also to submit the changes introduced from version 1.0 to version 2.0 of the proposed Phase 2 protocol FS118-21201. Accordingly, the proposal will be deliberated in the forthcoming SEC.