

Recommendations of the SEC (Oncology & Haematology) made in its 115th meeting held on 09.12.2021& 10.12.2021 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/IMP/21/000090 Tepotinib Film coated tablets 250 mg	M/s. Merck Specialities Private Limited	<p>The firm presented the proposal for import and marketing of Tepotinib film coated tablets 250 mg along with justification for local clinical trial waiver based on phase II clinical trial data.</p> <p>The committee noted that the drug was approved and designated as Orphan drug under accelerated approvals in USA, Japan, United Kingdom, Australia S. Korea, Brazil, Switzerland and Taiwan and also the indication “for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) harbouring MET tyrosine kinase receptor exon14 (METex14) skipping alterations” which is a serious/ life threatening and rare condition for which there is unmet medical need.</p> <p>Presently the drug has received “Accelerated Approval” from US FDA on the basis of Phase II data, without the conduct of a Phase III trial, with a rider that “Continued approval of this indication may be contingent upon verification and description of clinical benefit in confirmatory trials”.</p> <p>After detailed deliberation, the committee recommended for the grant of permission to import and marketing of the drug with local clinical trial waiver for the proposed indication subject to the condition that the firm should include Indian patients in the confirmatory global phase III clinical trial.</p>
2.	ND/CT/000090 Darolutamide 300mg film coated tablets	M/s. Bayer Pharmaceuticals Pvt. Ltd	<p>The firm presented the proposal for conduct of Phase IV clinical trial with Darolutamide 300mg film coated tablets before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV trial along with sample size justification to CDSCO.</p>

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Biological Division			
3.	4-394/Roche/16-BD (Pt-I) Atezolizumab	M/s. Roche Products (India) Pvt Ltd	The firm didn't turn up for presentation.
4.	4-350/BMS/160BD (Part-I) Nivolumab	M/s. Bristol Myers Squibb	The firm didn't turn up for presentation.
5.	4-88/Roche/PAC-R-Obinutuzumab/2021-BD Obinutuzumab	M/s. Roche Products India Pvt. Ltd	<p>The firm presented the proposal for approval of additional indication and alternative infusion duration of the approved drug.</p> <p>The committee noted that the proposed additional indication is already approved by EMA.</p> <p>After detailed deliberation, the committee recommended for grant of approval for proposed indication and alternative infusion duration subject to condition that firm should submit PSUR for the proposed indication and as per the frequency mentioned in the rules and proposed duration of infusion.</p>
6.	BIO/IMP/21/000103 Daratumumab	M/s. Johnson & Johnson Pvt. Ltd	<p>The firm presented the proposal for change in indication of the drug.</p> <p>The committee noted that the indication is same as that approved earlier and the text is revised to align with EMA approval.</p> <p>After detailed deliberation, the committee recommended for grant of approval for the proposed changes.</p>
7.	4-04/Intas/PAC-R-Romiplostim/2021-BD Romiplostim	M/s. Intas Pharmaceutical	<p>The firm presented the proposal for additional indication of the approved drug.</p> <p>The committee noted that the indication is approved by US FDA for the reference product.</p> <p>After detailed deliberation, the committee recommended for grant of approval for the proposed additional indication.</p>
8.	4-30/Roche/PAC-R-Atezilizumab/19-BD (Pt-II)	M/s. Roche Products India Pvt. Ltd	The firm didn't turn up for presentation.

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	Atezolizumab		
9.	BIO/IMP/21/000048 Luspatercept 25mg & 75 mg	M/s. BMS	<p>In light of earlier recommendations of the SEC dated 08.09.2021 & 09.09.2021, the firm presented their proposal for waiver of Phase IV clinical trial.</p> <p>The committee noted that marketing authorization of the drug was recommended with waiver of local Phase III clinical trial and with condition to conduct Phase IV study.</p> <p>After detailed deliberation, the committee reiterated the previous recommendation to conduct Phase IV study.</p>
SND Division			
10.	SND/MA/21/0000504 Hydroxyurea Capsules 500 mg	M/s. Cipla Limited	<p>The firm presented their proposal for manufacturing & marketing of Hydroxyurea capsules 500mg along with published data for the indication, prevention of recurrent painful vaso-occlusive crises including acute chest syndrome in adults, adolescents and children older than 2 years suffering from symptomatic sickle cell syndrome.</p> <p>The committee noted that Hydroxyurea capsules 500mg is already approved for the said indication in US, UK & included in National guideline.</p> <p>After detailed deliberation, the committee recommended for grant of permission to marketing Hydroxyurea capsules 500mg for the applied indication subject to condition that firm should conduct PMS Study.</p> <p>Accordingly, the firm should submit PMS study protocol within 03 months of approval of the product.</p>
11.	SND/MA/21/000506 Enzalutamide Solution 32mg/ml (160mg/5ml)	M/s. BDR Pharma	<p>The firm presented their proposal for manufacturing & marketing of Enzalutamide Solution 32mg/ml (160mg/5ml) for already approved indication along with BE study protocol.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the BE Study & present the results of the BE study should presented</p>

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			for review by the committee.
12.	SND/MA/21/000323 Tranexamic Acid Spray 10% w/v	M/s. Shilpa Medicare	In light of earlier SEC (Oncology) recommendation dated 07.10.2021 & 08.10.2021 the firm presented Phase III clinical trial protocol before the committee. After detailed deliberation, the committee opined that the firm should submit revised well structured protocol with clearly defined inclusion and exclusion criteria and the criteria should be rationale with the study objectives.
GCT Division			
13.	CT/23/20Online Submission(11192) Durvalumab in combination with Gemcitabine plus Cisplatin	M/s. AstraZeneca	The firm presented their protocol Amendment to study protocol no.D933AC00001, Version 07 dated 01.03.2021 before the committee. After detailed deliberation, the committee recommended for grant of approval for the proposed protocol amendment.
14.	CT/99/20Online Submission(11569) TrastuzumabDeruxtec an (T-DXd)	M/s. AstraZeneca	In light of earlier recommendation dated 07.10.2021 & 08.10.2021, the firm presented their justification before the committee for the study protocol no.D967JC00001, protocol Version 02 dated 15.12.2020. After detailed deliberation, the committee recommended for grant of approval for the proposed protocol amendment.
15.	CT/29/19Online Submission(12282) Dated16/08/21 Capivasertib+ Paclitaxel	M/s. AstraZeneca	The firm presented their protocol amendment protocol no.D3614C00001, protocol version 6.0 dated 11.05.2021 before the committee. After detailed deliberation, the committee recommended for grant of approval for the proposed protocol amendment.
16.	CT/103/21OnlineSub mission(27565) Dated20/08/21 TrastuzumabDeruxtec an (T-DXd, DS- 8201a)	M/s. AstraZeneca	The firm presented their Phase III clinical trial proposal before the committee. Assessment of risk versus benefit to the patients- The safety profile of the study drug from preclinical and clinical studies justify the conduct of the trial. Innovation vis-a-vis existing therapeutic- To assess the efficacy and

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			<p>safety of Trastuzumab Deruxtecan as first-line treatment of unresectable, locally advanced, or metastatic NSCLC harboring HER2 exon 19 or 20 mutations (DESTINY-Lung04).</p> <p>Unmet medical need in the country- The test drug used for first-line treatment of unresectable, locally advanced, or metastatic NSCLC harboring HER2 exon 19 or 20 mutations (DESTINY-Lung04).</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial study subject to condition that firm need to increase number of subjects to atleast 25 from India.</p>
17.	CT/79/18Online Submission(12384) Dated25/08/21 Durvalumab	M/s. AstraZeneca	<p>The firm presented their protocol amendment protocol no. D933YC00001, Version 5.0 dated 26May2021 before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of approval for the proposed protocol amendment.</p>
18.	CT/68/20Online Submission (12769) Dated25/08/21 Amivantamab and Lazertinib	M/s. J&J	<p>The firm presented their Protocol amendment protocol no 73841937NSC3003, protocol amendment 2.0 dated 23 Sep 2021 before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of approval for the proposed protocol amendment.</p>
19.	CT/36/21Online Submission(13284) Dated28/10/21 Talazoparib With Enzalutamide	M/s. Pfizer	<p>The firm presented their Protocol amendment to study protocol no.C3441052, protocol amendment 1, dated 20Sept 2021 before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of approval to the proposed protocol amendment.</p>
20.	CT/15/19Online Submission(13317) Dated28/10/21 Fitusiran	M/s PPD	<p>The firm presented their protocol amendment to the study protocol no.LTE15174, protocol amendment 4, dated 30 Sept 2021 before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of approval for</p>

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			the proposed protocol amendment.
21.	CT/117/21OnlineSubmission(28134) Dated 18/09/21 Datopotamabderuxtec an (Dato-DXd, DS1062a)100mg	M/s. AstraZeneca	<p>The firm presented their Phase III clinical trial proposal before the committee.</p> <p>Assessment of risk vs. Benefit to the patients: The safety profile of the study drugs from preclinical toxicology studies including repeat dose toxicity study and Phase I & II clinical study data justify the conduct of the trial.</p> <p>Innovation vis-à-vis Existing Therapeutic option: The purpose of the study is to demonstrate the superiority of Dato-DXd compared to ICC by assessment of PFS in participants with inoperable or metastatic HR-positive, HER2-negative breast cancer, who have been treated with 1 or 2 lines of chemotherapy in the inoperable/metastatic setting, per BICR.</p> <p>Unmet Medical need in the country: The test drug may potentially provide treatment in patients with Inoperable or Metastatic Hormone Receptor-Positive, HER2-Negative Breast Cancer who have been treated with one or two prior lines of systemic chemotherapy.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the study.</p>
22.	CT/11/21OnlineSubmission(12801) Erdafitinib	M/s. J & J	<p>The firm presented their protocol amendment to study protocol no 42756493BLC2003, protocol amendment 4.0 dated 08 Feb 2021 before the committee.</p> <p>After detailed deliberation, the committee opined that the firm should submit 6mg per day of Erdafitinib ADR/tolerability data for further review by the committee.</p>
23.	CT/140/21OnlineSubmission(28659) Dated22/10/21 IMM-101	M/s. JSS	<p>The firm presented their Phase III clinical trial proposal before the committee.</p> <p>Assessment of risk versus benefit to the patients- The safety profile of the study drug from preclinical and clinical studies justify the</p>

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			<p>conduct of the trial.</p> <p>Innovation vis-a-vis existing therapeutic:-</p> <p>To evaluate the safety and efficacy of IMM-101 in combination with Gemcitabine and Nab-Paclitaxel (Gem/Nab-P) as a first line therapy in poor performance status (PS) or elderly patients with Metastatic Pancreatic Ductal Adenocarcinoma (mPDAC).</p> <p>Unmet medical need in the country-</p> <p>The test drug used for as a first line therapy in poor performance status (PS) or elderly patients with Metastatic Pancreatic Ductal Adenocarcinoma (mPDAC).</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the study subject to condition that firm needs to submit DSMB report of first 30 patients to review further continuation of the study by the committee.</p>
24.	<p>CT/148/21OnlineSubmission(29045) Dated15/11/21</p> <p>Paclitaxel- Carboplatin- Oregovomab)</p>	M/s. Star Genomics	<p>The firm submitted Phase III proposal before the committee.</p> <p>Assessment of risk vs. Benefit to the patients:</p> <p>The safety profile of the study drugs from preclinical toxicology, Phase I & II studies including repeat dose toxicity study justify the conduct of the trial.</p> <p>Innovation vis-à-vis Existing Therapeutic option:</p> <p>To determine the efficacy by progression free survival (using investigator assessment of scans according to RECIST v1.1) of Oregovomab compared to placebo when administered with background chemotherapy (Paclitaxel/Carboplatin) to subjects with newly diagnosed ovarian cancer (FIGO Stage III or IV) who have undergone optimal debulking surgery.</p> <p>Unmet Medical need in the country:</p> <p>The test drug may potentially provide treatment in patients with Advanced</p>

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			Epithelial Ovarian, Fallopian Tube or Peritoneal Carcinoma. After detailed deliberation, the committee recommended for grant of permission to conduct the study.
25.	CT/13/20 Online Submission (13762) Dated 18/11/21 Osimertinib	M/s. AstraZeneca	The firm presented their Protocol amendment to study protocol no. D5169C00001, protocol amendment 1.0 dated 26 Aug 2021 before the committee. After detailed deliberation, the committee recommended for grant of approval for the proposed protocol amendment.
26.	CT/66/21 Online Submission (13868) Dated 22/11/21 PTG-300	M/s. JSS	The firm presented their protocol amendment to study protocol no. PTG-300-04, protocol amendment 8.0 dated 21 Oct 2021 before the committee. After detailed deliberation, the committee recommended for grant of approval for the proposed protocol amendment.