

Recommendations of the SEC (Oncology & Haematology) made in its 114th meeting held on 11.11.2021 & 12.11.2021 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/MA/19/000077 Tegafur, Gimeracil and Oteracil capsules (15mg/4.35mg/11.8 mg and 20mg/5.8mg/15.8mg)	M/s. BDR Pharmaceuticals International Pvt. Ltd	In light of SEC recommendations dated 07.10.2021 and 08.10.2021, the firm presented their proposal along with patient referral and gastrectomy details. After detailed deliberation, the committee recommended for grant of permission to manufacture the drug. Further, it was opined that post approval verification may be done by CDSCO at the study site to verify the BE data.
Biological Division			
2.	BIO/CT/18/FF/2021/27039 Nivolumab	M/s. Bristol-Myers Squibb India Pvt. Ltd	The firm presented their proposal for additional indications of the drug. The committee noted that the proposed indications are already approved in US, EU, etc. After detailed deliberation, the committee recommended for grant of approval for the proposed additional indications of the drug
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.	BIO/CT04/FF/2021/28204 Pegfilgrastim	M/s. Intas Pharmaceuticals Ltd	The firm presented proposal for conduct of Phase III clinical trial of already approved drug in pediatric population for export purpose. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as per the proposed protocol.
5.	BIO/CT04/FF/2021/25033 Trastuzumab Emtasine	M/s. Cadila Healthcare Limited	The firm presented the proposal for conduct of Phase IV clinical trial before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial with the condition that the sample size should not be less than 200 patients.
6.	BIO/CT04/FF/2021/28047	M/s. Accutest Research	The firm presented proposal for conduct of PK study of the drug with use of On

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	Pegfilgrastim	Laboratories(I) Pvt. Ltd.	Body Injector. After detailed deliberation, the committee recommended for grant of permission to conduct the PK study as per presented protocol.
7.	4-54/Cadila/PAC-R-Trastuzumab (375 mg)/2020-BD Trastuzumab 375 mg	M/s. Cadila Healthcare Limited	The firm presented the proposal for additional strength viz 375mg along with their justification for the additional strength. The committee noted that the same strength is already approved for marketing in the country. After detailed deliberation, the committee recommended for grant of approval for the additional strength of 375 mg of the drug.
8.	BIO/CT/21/000131 Pertuzumab	M/s. Cadila Healthcare Limited	The firm presented the proposed Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial.
SND Division			
9.	SND/IMP/20/000015 Olaparib 100/150 mg Film Coated Tablet	M/s. AstraZeneca	Earlier the proposal of the firm was deliberated in SEC meeting held on 08.09.2021 & 09.09.2021 and the committee did not agree to the request made by the firm and recommended that Vascular Thromboembolism (VTE) should be included in “warning & precaution” section in pack insert of Olaparib film coated tablets 100mg & 150mg as justification presented for non-inclusion of the same was not adequate. In the present meeting, the firm presented another clinical data and the committee opined that the firm should submit complete data in totality for further consideration of revision in the pack insert.
10.	SND/MA/21/000372 Enzalutamide Tablets 160mg	M/s. BDR Pharma	The firm presented their proposal along with BE study report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture sEnzalutamide Tablets

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			160mg with already approved indications in India.
GCT Division			
11.	CT/28/19 Online Submission (11395) Osimertinib+ Savolitinib	M/s. AstraZeneca	The firm presented their protocol amendment to study protocol no. D5084C00007, Version 06 dated 22 Feb 2021 before the committee. After detailed deliberation, the committee recommended for grant of approval to the proposed protocol amendment.
12.	CT/10/19 Online Submission (11690) Durvalumab	M/s. AstraZeneca	The firm presented their protocol amendment to study protocol no. D9106C00001, Version 04 dated 15 Apr 2021 before the committee. After detailed deliberation, the committee recommended for grant of approval to the proposed protocol amendment.
13.	CT/89/21 Online Submission (27336) Leutium	M/s. PSI-CRO	The firm presented their Phase III clinical trial protocol 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 option- To Evaluate Efficacy, Safety and Patient-reported Outcomes of Peptide Receptor Radionuclide Therapy (PRRT) with Lutetium (177Lu) Edotreotide compared to Best Standard of Care in Patients with Well-differentiated Aggressive Grade 2 and Grade 3, Somatostatin Receptor positive (SSTR+), Neuroendocrine tumors of Gastro Enteric or Pancreatic Origin (COMPOSE) Unmet medical need in the country- The test drug used for Neuroendocrine Tumors of Gastro Enteric or Pancreatic Origin (COMPOSE). After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial.

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14.	CT/101/21 Online Submission (27402) Dabrafenib Plus Trametinib	M/s. Novartis	<p>The firm presented the Phase III study protocol no. CDRB436J12301, Version number: 00, dated: 12.01.2021 before the committee.</p> <p>Risk versus benefit to the patients- The safety profile of the study drug from preclinical and clinical studies justify the conduct of the trial. Dabrafenib and Trametinib have already been approved in combination for multiple indications (i.e., metastatic melanoma, NSCLC) and thus the safety profile is well established.</p> <p>Innovation vis-a-vis existing therapeutic option- The current standard of care for patients who progress on VEGFR therapy is chemotherapy (Doxorubicin or Paclitaxel) or symptomatic management. There is an unmet need in patients with advanced metastatic differentiated thyroid carcinoma who are refractory to radioactive iodine and have progressed following prior VEGFR targeted therapy.</p> <p>Unmet medical need in the country- Based on the preliminary data, it is expected that Dabrafenib in combination with Trametinib will target the inhibition of radioiodine uptake and remodelling of metabolic pathways mediated by hyperactive BRAFV600E that could be beneficial for the patients.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial.</p>
15.	CT/109/21 Online Submission (27803) INTP24	M/s. Intas Pharma	<p>The firm presented Phase III clinical trial protocol no. 0289-21, Version 1.0 dated 18 Aug 2021 before the committee.</p> <p>Risk versus benefit to the patients- The safety profile of the study drug from preclinical and clinical studies justify the conduct of the trial.</p> <p>Innovation vis-a-vis existing therapeutic option- To establish therapeutic equivalence of Bevacizumab- Intas to Bevacizumab-ref in participants with unresectable, locally advanced or metastatic non-squamous</p>

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			<p>non-small cell lung cancer.</p> <p>Unmet medical need in the country- Innovator is available in Indian market or available in global market and can be imported to India. Accessibility of innovator product is limited to Indian population due to cost and this is the main concern.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial.</p>
16.	<p>CT/110/21 Online Submission (27499)</p> <p>Asciminib</p>	M/s. Novartis	<p>The firm presented Phase III clinical trial protocol before the committee.</p> <p>Risk versus benefit to the patients- The safety profile of the study drug from preclinical and clinical studies justify the conduct of the trial.</p> <p>Innovation vis-a-vis existing therapeutic option-</p> <ul style="list-style-type: none"> • To compare the efficacy of Asciminib versus Investigator selected TKI with respect to the proportion of patients that are in Major Molecular Response (MMR) at Week 48. • To compare the efficacy of Asciminib versus Investigator selected TKI, within the stratum of patients with Imatinib as the pre-randomization selected TKI, with respect to the proportion of patients that are in MMR at Week 48 <p>Unmet medical need in the country- The drug to be used for the treatment of Philadelphia Chromosome Positive Chronic Myelogenous Leukemia in Chronic Phase.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial.</p>
17.	<p>CT/25/20 Online Submission (12456)</p> <p>Alpelisib (BYL719)</p>	M/s. Novartis	<p>The firm presented major protocol amendment to study protocol no. CBYL719H12301, Protocol Amendment Version 01 dated 25 May 2021 before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of approval to the protocol amendment.</p>

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18.	CT/29/21 Online Submission (12537) Larotrectinib (BAY2757556)	M/s. Bayer	<p>The firm presented their protocol amendment to study protocol no. BAY 2757556/20289 Protocol Amendment Version 11.0 dated 21 June 2021 before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of approval to the protocol amendment.</p>
19.	CT/123/21 Online Submission (28276) Trastuzumab Deruxtecan (T-DXd)	M/s. AstraZeneca	<p>The firm presented their Phase III clinical trial protocol 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 conduct of the trial.</p> <p>Innovation vis-a-vis existing therapeutic option- Neoadjuvant Trastuzumab Deruxtecan (T-DXd) Monotherapy or T-DXd followed by THP compared to ddAC-THP in participants with High-risk HER2-positive Early-stage Breast Cancer (DESTINY-Breast11)</p> <p>Unmet medical need in the country- The test drug used for High-risk HER2-positive Early-stage Breast Cancer (DESTINY-Breast11).</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial.</p>
20.	CT/38/21 Online Submission (12733) JNJ-42756493	M/s. J&J	<p>The firm presented their protocol amendment to study protocol no. 42756493BLC2001, Protocol Amendment Version 8 dated 03 Aug 2021 before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of approval to the protocol amendment.</p>
21.	CT/138/21 Online Submission (28645) Crizanlizumab	M/s. Novartis	<p>The firm presented the roll over study Phase IV protocol before the committee.</p> <p>Risk versus benefit to the patients- The study drug is already approved in India, its safety profile may justify the conduct</p>

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			<p>of the trial.</p> <p>Innovation vis-a-vis existing therapeutic option- The objective of this study to allow access of Crizanlizumab to patients with SCD who are on Crizanlizumab treatment.</p> <p>Unmet medical need in the country- The test drug may be alternative treatment option in pediatrics with SCD.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the trial with the condition that the firm should provide the post trial access of the drug till the patients getting benefited from the Crizanlizumab or not developing any side effect. Accordingly, the firm should submit protocol addendum to CDSCO w.r.t protocol section 4.2 and 6.1.5 treatment duration.</p>
22.	<p>CT/97/21 Online Submission (27556)</p> <p>Amivantamab& Lazertinib</p>	M/s. Johnson & Johnson	<p>The firm presented their Phase III clinical trial protocol before the committee.</p> <p>Assessment of risk vs. benefit to the patients: The safety profile of the study drugs from preclinical toxicology, Phase I & Phase II studies including repeat dose toxicity study justify the conduct of the trial.</p> <p>Innovation vis-à-vis Existing Therapeutic option: To assess the efficacy of LACP, compared with CP, in participants with locally advanced or metastatic EGFR Exon 19del or Exon 21 L858R substitution NSCLC.</p> <p>Unmet Medical need in the country: The test drug may potentially provide treatment in Patients with EGFR-Mutated Locally Advanced or Metastatic Non-Small Cell Lung Cancer after Osimertinib Failure</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial.</p>
23.	<p>CT/111/20 Online Submission (11543)</p> <p>Trastuzumab Deruxtecan (T-DXd, DS-820 1a)</p>	M/s. AstraZeneca	<p>The firm presented their protocol amendment to study protocol no. D967VC00001, Protocol Amendment Version 02 dated 02 Feb 2021 before the committee.</p> <p>After detailed deliberation, the committee</p>

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			recommended for grant of approval to the protocol amendment.