

Recommendations of the SEC (Oncology & Haematology) made in its 133rd meeting held on 27.09.2022 & 29.09.2022 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/IMP/22/000047 Niraparib Tablet 100 mg	M/s. GSK Pharma India Pvt. Ltd.	<p>The firm presented their proposal for import and marketing of the drug Niraparib Tablets 100mg along with justification for local phase –III clinical trial waiver before the committee.</p> <p>The committee noted that Niraparib tablet formulation is approved in countries including the European Union, Singapore and the drug is indicated for a disease which is serious and 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 marketing of Niraparib Tablets 100mg subject to the following conditions that the firm should conduct Phase IV clinical trial in the country for which the protocol should be submitted to CDSCO within two months of approval of the drug for further review by the committee.</p>
SND Division			
2.	SND/MA/22/000220 Feracrylum 1% mouth gargle	M/s. Themis Medicare	<p>The firm presented their proposal for manufacture and marketing of Feracrylum 1% mouth-gargle for the additional indication “Oral Mucositis” with request of local clinical trial as well as BE study waiver before the committee.</p> <p>After detailed deliberation, the committee did not agree with the request of waiver of local clinical trial as well as BE study; therefore the firm should submit Phase III clinical trial protocol before the committee for further review.</p>

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3.	SND/MA/22/000054 Rucaparib Tablets 200/300 mg	M/s. Beta Drugs	<p>The firm presented their proposal of BE study waiver for Rucaparib Tablets 200/300mg with justification and different challenges in recruitment of patients for the study before the committee.</p> <p>The committee noted that Rucaparib is not a drug of BCS class I and III. After detailed deliberation, the committee recommended that the firm should explore other CRO or multi centric BE study for study of the applied drug with respect to regulatory aspects and New Drugs Clinical Trial Rules'2019.</p>
4.	SND/MA/22/000104 6-Mercaptopurine Powder for oral suspension 10 mg/ml	M/s. IDRS Labs	<p>The firm presented their proposal of manufacture and marketing of 6-Mercaptopurine Powder for oral suspension 10 mg/ml alongwith BE study report and justification of higher bioavailability in suspension dosage form of 6-marcaptopurine over tablets dosage form before the committee.</p> <p>After detailed deliberation the committee recommended for grant of manufacture and marketing permission of 6-Mercaptopurine Powder for oral suspension 10mg/ml for proposed indication as <i>“Treatment of acute lymphoblastic leukemia”</i> subject to condition that, firm should conduct Phase-IV clinical trial. Accordingly, the firm should submit Phase-IV study protocol within one year after marketing.</p>
Biological Division			
5.	BIO/IMP/18/0000006 Inotuzumab Ozogamicin	M/s. Pfizer Products	<p>The firm presented the proposal for amendment in the warning statement for already approved drug product-Inotuzumab Ozagamicin 1 mg powder for concentrate for solution for infusion from current warning statement “To be sold by retail on the prescription of an Oncologist only” to “To be sold by retail on the prescription of an Oncologist & Hematologist only”.</p> <p>After detailed deliberation, the committee recommended for the proposed amendment in the warning statement as “To be sold by retail on the prescription</p>

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			of an Oncologist & Clinical Hematologist only”.
6.	BIO/CT/22/000035 Pertuzumab +Trastuzumab (Phesgo)	M/s. Roche Products (India) Pvt. Ltd.	<p>Firm presented the proposal for conduct of Phase IV study titled “A Phase IV, Randomized, Multicenter, Open-Label, Crossover Study to Evaluate the Safety and Efficacy of Subcutaneous Administration of the Fixed-Dose Combination of Pertuzumab and Trastuzumab (Phesgo) in Indian Patients with HER2-Positive Breast Cancer”.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV trial as per the presented protocol. Also the committee opined that the observation period post drug administration should be extended to 1 hour from 30 minutes.</p>
7.	BIO/CT/20/000088 Recombinant Human Serum Albumin 20%	M/s Lazuline Biotech Pvt. Ltd.	<p>In light of SEC recommendation dated 12.04.2022, the firm presented revised protocol titled “An Open Label, Randomized, Three Dose, Parallel, Safety, Tolerability, Immunogenicity Assessment Study of Recombinant Human Albumin followed by Pharmacokinetic comparison with Plasma Derived Human Serum Albumin in Healthy Adults”.</p> <p>After detailed deliberation, the committee recommended for grant of permission for conduct of the study with the following conditions:</p> <ol style="list-style-type: none"> 1. Additional dose of 5 g to be included in the Part 1 (safety and tolerability) of the study. 2. Allergy test to be carried out during screening of the subjects. 3. Age group should be 18-55 years instead of 18-45 years for inclusion of the subjects. 4. Interim results of Part I of the study should be submitted for review before initiation of Part 2 of the study. <p>Accordingly, the revised protocol should be submitted to CDSCO for review.</p>

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GCT Division			
8.	CT/59/22 Online submission (32828) Ceralasertib (AZD6738 + Durvalumab)	M/s. Parexel	The firm presented the proposed study protocol no. D533BC00001, Version 1.0 dated 21-MAR-2022 (LATIFY) before the committee. After detailed deliberation the committee recommended for the conduct of the study as per study protocol with condition that: 1) SAEs irrespective of its causality are to be reported to CDSCO as per the provision of New Drugs and Clinical Trial Rules 2019 during the study and its follow up period. Therefore, the applicant is required to submit an India specific protocol addendum for the SAE reporting in the proposed study as per Rules. 2) The PI of the proposed site should have experienced Medical Oncologist and also to include more number of Govt. sites in the study.
9.	CT/79/22 Online Submission (33423) BCD-217 (Nurulimab+ Prolgolimab)	M/s. IR Innovate Research	The applicant has presented phase III clinical trial protocol no BCD-217-2/OCTAVA version 1.0 IND dated 10/06/2022 before the committee. After detailed deliberation, the committee opined that the study should be conducted as Phase II/III rather than Phase III in India and accordingly revised Phase II/III protocol should be submitted to CDSCO for further review by the committee.