

Recommendations of the SEC (Cardiovascular & Renal) made in its 91st meeting held on 08.10.2021 and 11.10.2021 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/IMP/21/000062 Inclisiran Solution for Injection in pre-filled syringe 284 mg/1.5 mL	M/s Novartis Healthcare Pvt. Ltd	<p>The firm presented their proposal for import and marketing of the drug with local clinical trial waiver before the committee.</p> <p>The committee observed that, justification for local clinical trial waiver was not adequate as per Rules and there is no unmet medical need for the proposed indication in the country.</p> <p>After detailed deliberation, the committee did not recommend for local clinical trial waiver and opined that, the firm should conduct Phase III clinical trial in the country.</p> <p>Accordingly, the firm should submit the Phase III clinical trial protocol to CDSCO for further review by the committee.</p>
2.	ND/IMP/20/000061 Ferric Pyrophosphate Citrate Solution, 27.2 mg Fe/5 ml)	M/s Sun Pharma Laboratories	<p>In light of earlier recommendation of SEC dated 25.07.2020 & Technical committee recommendation dated 26.04.2021 the firm presented Phase III clinical trial before the committee.</p> <p>After detailed deliberation, the committee opined that</p> <ol style="list-style-type: none"> 1. Range for upper limit of serum ferritin and TSAT for giving Ferric Pyrophosphate Citrate in the treatment arm should be included in the inclusion criteria. 2. Test for Folic acid and Vitamin B12 deficiency need to be performed before inclusion of patients in the study. 3. Hepatitis B, Hepatitis C, Occult TB and latent TB test should be performed for exclusion of patients from the study and Lab investigations and documents shall be maintained . 5. Primary End points should be Hb and iron markers (TSAT, Ferritin, TIBC etc.) rather than IV iron as rescue therapy

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			6. During the conduct of the trial, during Phase-II of the study, change in ESA, blood transfusion and use of any form of iron should be clearly defined. Accordingly firm should submit revised clinical trial protocol to CDSCO for further review by the committee.
3.	ND/IMP/21/000076 Vericiguat 2.5 mg/5 mg/10 mg Film coated tablet	M/s Bayer Pharmaceuticals Pvt. Ltd.	<p>The firm presented their proposal for import and marketing of the drug with local clinical trial waiver and justification for unmet medical need before the committee and commitment for conducting Phase IV clinical trial before the committee.</p> <p>After detailed deliberation, the committee opined that the firm should submit specific justification/ advantages of the drug over the available drug for the proposed indication with supportive documentary evidence to consider the matter further.</p>
4.	ND/MA/20/000097 Bempedoic acid 180 mg+ Ezetimibe 10 mg tablet	M/s Akums Drugs and Pharmaceuticals Ltd.	<p>In light of the earlier SEC recommendation dated 16th Sep 2021 the firm presented BA/BE study report.</p> <p>After detailed deliberation, the committee recommended that the results of BE study to be forwarded to the member Pharmacologist of the committee for further consideration.</p>
SND Division			
5.	SND/IMP/20/000105 Empagliflozin 10mg/25 mg tablet	M/s Boehringer	<p>In light of earlier SEC recommendation dated 09.03.2021 & 10.03.2021, the firm presented the USFDA approval details for Empagliflozin Tablets 10/25mg as new indication to reduce the risk of cardiovascular death plus hospitalization for heart failure in adults with heart failure and reduced ejection fraction.</p> <p>After detailed deliberation, the committee recommended for grant of permission for marketing the drug for additional indication to reduce the risk of cardiovascular death plus hospitalization for heart failure in adults with heart failure and reduced ejection fraction.</p> <p>The committee also opined that the proposal of updation of package insert</p>

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			should be deliberated separately.
6.	SND/CT/21/000081 Edaravone Oral Suspension 150 mg (30mg/ml)	M/s BDR Pharmaceuticals	The firm presented their proposal for permission to conduct Bioavailability Study for Edaravone Oral Suspension 150 mg (30mg/ml) before the committee. However, the committee recommended that the proposal should be deliberated in SEC (Neurology and Psychiatry) as the said indication is for the improvement of neurological symptoms, a disorder of activities of daily living and disorder associated with acute ischemic stroke.
FDC Division			
7.	FDC/MA/19/000106 Efonidipine Hydrochloride Ethanolate +Telmisartan IP (20mg/20mg/40mg+20mg/40mg/40mg)uncoated bilayered tablet	M/s. Zuventus Healthcare Ltd.	The firm presented the BE and Phase III CT report before the committee on the FDC of Efonidipine Hydrochloride Ethanolate + Telmisartan IP (40mg+40mg) uncoated bilayered tablet. After detailed deliberation, the committee opined that primary data of the clinical trial results should be submitted by the firm within 2 days in Excel format which may be circulated to the committee members for further review and recommendations.
8.	FDC/MA/20/000077 Azelnidipine + Metoprolol (SR) (8mg/8mg/16mg/16mg + 25mg/50mg/25mg/50m) Tablet	M/s Akums drugs & pharmaceuticals limited	The firm presented the BE report before the committee. After detailed deliberation, the committee opined that firm may initiate the Phase III clinical trial as per approved protocol for which permission has already been issued by CDSCO.
9.	FDC/IMP/20/000021 Zinc chloride =1050.0000 micrograms (µg) E.P. Active Sodium fluoride =210.0000 micrograms (µg) E.P. Active Potassium iodide =16.6000 micrograms (µg) E.P. Active Sodium molybdatehydrate =4.8500 micrograms (µg) E.P. Active	M/s Fresenius kabi	The firm presented their proposal along with Phase IV clinical trial waiver request before the committee. The committee noted that the firm has not yet submitted Phase IV CT protocol inspite of grant of approval of the drug on 03.07.2020. After detailed deliberation, the committee did not consider the request of the firm for Phase IV clinical trial waiver and the committee recommended that the firm should submit Phase IV CT protocol within 45days for review by the committee.

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	Sodium selenite anhydrous =17.2900 micrograms (µg) In House Specification Active Copper chloride ehydrate =102.3000 micrograms (µg) U.S.P. Active Manganese chloridetetrahydrate =19.7900 micrograms (µg) U.S.P. Active Ferric chloride hexahydrate =540.0000 micrograms (µg) E.P. Active Chromic chloride hexahydrate =5.3300 micrograms (µg) U.S.P		
GCTDivision			
10.	CT/65/21 Online Submission (26521) LIB003	M/s. Medpace	<p>The firm presented the clinical trial protocol no. LIB003-004, Version No. 1.0 dated 21 Oct 2020 before the committee.</p> <p>Risk-Benefit Assessment: LIB003 has been well tolerated in nonclinical studies and clinical studies that have been conducted to date, which have demonstrated an acceptable safety profile for LIB003 to support the initiation of this Phase 3 clinical study.</p> <p>Innovation Vs Existing Therapy: Based on the pre-clinical studies and the clinical studies, LIB003 has been shown a highly selective and potent inhibitor of PCSK9 and provide substantial, additional LDL-C lowering when added to stable and maximally tolerated statin, or statin plus Ezetimibe, similar to existing mAb treatments.</p> <p>Unmet Need: LIB003 is being developed as an</p>

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			<p>adjunct SC therapy for the reduction of LDL-C in patients with Heterozygous Familial Hypercholesterolemia who are on stable lipid-lowering therapy requiring a additional LDL-C reduction.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed clinical trial as per the protocol presented.</p>
11.	CT/96/21 Online Submission (27532) LIB003	M/s Medpace	<p>The firm presented the clinical trial protocol no. LIB003-005, version No. 1.0 dated 21 Oct 2020 before the committee.</p> <p>Risk-Benefit Assessment: LIB003 has been well tolerated in nonclinical studies and clinical studies that have been conducted to date, which have demonstrated an acceptable safety profile for LIB003 to support the initiation of this Phase 3 clinical study.</p> <p>Innovation Vs Existing Therapy: Based on these pre-clinical studies and the clinical studies, LIB003 has been shown a highly selective and potent inhibitor of PCSK9 and provide substantial, additional LDL-C lowering when added to stable and maximally tolerated statin, or statin plus Ezetimibe, similar to existing mAb treatments.</p> <p>Unmet Need: LIB003 is being developed as an adjunct SC therapy for the reduction of LDL-C in patients with high risk for cardiovascular disease on who are stable lipid-lowering therapy requiring additional LDL-C reduction.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed clinical trial as per the protocol presented.</p>
12.	CT/78/21 Online Submission (27028)	M/s. Medpace	<p>The firm presented the clinical trial protocol no. LIB003-006, Version No. 1.0 dated 21 Oct 2020 before the committee.</p>

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	LIB003		<p>Risk-Benefit Assessment: LIB003 has been well tolerated in nonclinical studies and clinical studies that have been conducted to date, which have demonstrated an acceptable safety profile for LIB003 to support the initiation of this Phase 3 clinical study.</p> <p>Innovation Vs Existing Therapy: Based on these pre-clinical studies and the clinical studies, LIB003 has been shown a highly selective and potent inhibitor of PCSK9 and provide substantial, additional LDL-C lowering when added to stable and maximally tolerated statin, or statin plus Ezetimibe, similar to existing mAb treatments.</p> <p>Unmet Need: LIB003 is being developed as an adjunct SC therapy for the reduction of LDL-C in patients with cardiovascular disease or at high risk for cardiovascular disease, who are on stable lipid-lowering therapy requiring additional LDL-C reduction. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed clinical trial as per the protocol presented.</p>
13.	CT/82/21 Online Submission (27133) LNP023 (Iptacopan)	M/s. Novartis	<p>The firm presented Phase IIIB clinical trial protocol before the committee. After detailed deliberation, the committee did not recommend for grant of permission to conduct proposed clinical trial in its presented form due to following reasons:</p> <ol style="list-style-type: none"> 1. The Phase III study CLNP023A2301 from which the subjects will roll over in the proposed study has just started which will take almost 2 years to complete, hence roll over extension is not possible for those subjects at this stage. 2. The result of part I and part II of phase II study CLNP023X2203 was presented. The inclusion criteria for proposed roll over study should be based on the clinical data of these part I and part II of study CLNP023X2203

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			and not on the discretion of the investigator.
14.	CT/88/21 Online Submission (27132) Finerone/BAY94-8862	M/s. Bayer	The firm presented Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed clinical trial as per the protocol presented. (Dr. S.K. Agarwal did not participate in deliberation)
Biological Division			
15.	87/Phase IV/Amgen/17-BD (Pt-1)	M/s Amgen Technology Pvt. Ltd.	The firm presented clinical study report (CSR) for phase IV clinical trial for Evolocumab (Protocol No. 20170199) before the committee. After detailed deliberation, the committee noted the results of the study.