

Recommendations of the SEC (Neurology & Psychiatry) made in its 88th meeting held on 17.01.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/22/000066 Lasmiditan 50mg and 100mg tablets	M/s. Eli Lilly and Company (India) Pvt. Ltd.	The firm did not turn up for presentation.
Biological Division			
2.	BIO/IMP/22/000067 Ocrelizumab 300mg concentrate for solution for infusion	M/s Roche	<p>The firm presented the proposal to import and market Ocrelizumab 300mg concentrate for solution for infusion indicated for treatment of</p> <ul style="list-style-type: none"> • Relapsing forms of multiple sclerosis (RMS) to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease in adults. • Primary progressive multiple sclerosis (PPMS) in adults with local clinical trial waiver. <p>The firm presented the results of various global clinical trials conducted in the proposed indications. The drug product is approved in 100 countries globally including USA, EU, Canada, Switzerland, Australia.</p> <p>The committee noted that proposed indication of Primary progressive multiple sclerosis (PPMS) is a rare disease with no treatment available at present.</p> <p>The committee also noted that two global clinical trials (Study WN42086 and WA404040) are also planned in which India is one of the participating countries. After detailed deliberation, the committee recommended for grant of permission to import and market the drug for the proposed indications with the condition that:</p> <ol style="list-style-type: none"> (1) The firm should also submit post marketing safety data generated globally including Asian and Indian Population to CDSCO for review. (2) The firm should conduct Phase IV clinical trial.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			<p>(3) The firm should submit results of Global Clinical Trial proposed to be conducted in India once completed.</p> <p>Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within three months of import and marketing approval.</p>
3.	BIO/IMP/20/000088 Galcanezumab 120mg/ml injection	M/s Eli Lilly and Company	<p>In light of earlier recommendation of SEC dated 15.12.2020, the firm presented the Phase III global clinical trial results in which India was one of the participating countries for import and market of Galacanezumab 120mg/ml injection (single dose prefilled pen and prefilled syringe).</p> <p>The committee noted that the drug is approved in 48 countries globally including USA, EU, Japan, Switzerland, UK, Canada, Brazil, Australia.</p> <p>After detailed deliberation, the committee noted the results of the study and recommended for grant of permission to import and market the drug with the condition that the firm should conduct Phase IV clinical trial including evaluation with respect to neutralizing antibody as an endpoint.</p> <p>Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within three months of import and marketing approval.</p>
SND Division			
4.	SND/MA/22/000238 Caroverine Capsule 40 mg	M/s Lincoln Pharmaceuticals	The proposal was deferred for next meeting.
5.	SND/MA/22/000314 Brivaracetam Sustained Release Tablets 50mg/100mg/150mg	M/s Ravenbhel Healthcare	The proposal was deferred for next meeting.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
6.	FDC/MA/22/000359 Lacosamide 50mg/50mg + Brivaracetam 50mg/100mg tablets	M/s. Hetero Labs Ltd.	The proposal was deferred for next meeting.
7.	FDC/MA/22/000417 Bupropion HCl (As Extended release) 105mg + Dextromethorphan HBr 45 mg Tablet	M/s. Exemed	The proposal was deferred for next meeting.
GCT Division			
8.	CT/57/20 Online Submission (17881) Evobrutinib	M/s. IQVIA	In light of earlier SEC dated 18.11.2022, the applicant presented published safety data and specific data on AEs and SAEs of the investigational drug along with protocol version 4 dated 03.04.2022 before the committee After detailed deliberation, the committee recommended for the approval the proposed protocol amendment.
9.	CT/123/20 Online Submission (19011) Galcanzumab	M/s. Eli Lilly	The applicant has presented their proposal for protocol amendment I5Q-MC-CGAT(f) dated 22.04.2022 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
10.	CT/122/20 Online Submission (18950) Galcanzumab	M/s. Eli Lilly	The applicant presented its proposal for protocol amendment I5Q-MC-CGAS(h) dated 22.04.2022 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
11.	CT/120/22 Online Submission (34243)	M/s. Cliantha	The applicant presented its proposal for Phase II clinical trial protocol no. C2A01727: version 2 dated 15.09.2022

SEC (Neurology & Psychiatry) meeting dated 17.01.2023

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	Carbidopa + Levodopa (WD-1905)		before the committee. After detailed deliberation, the committee did not recommend for grant of permission to conduct the proposed study for the following reasons: <ol style="list-style-type: none"> 1. The design of the protocol is not scientifically justifiable. 2. Justification for selection of dosing at bed time of test drug (62.5/250 mg of WD- 1905) to conventional dose of reference products require further data. 3. More safety data is required to be submitted for the test drug.
12.	CT/115/22 Online Submission (34193) Fenebrutinib Compared with Ocrelizumab	M/s. Roche	The proposal was deferred for next meeting.
13.	CT/174/21 Online Submission (21211) SAR442168 to Teriflunomide (Aubagio®)	M/s. Sanofi	The applicant presented its proposal for protocol amendments PA 03, PA 04, PA 05, PA 06, and PA 07 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
14.	CT/121/22 Online Submission (33997) Pozelimab (REGN3918) & Cemdisiran (ALN-CC5)	M/s Paraxel	The applicant presented its Phase III clinical trial protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the study with condition that the sponsor/applicant should submit safety data bi-annually along with DMC recommendation for further review by the committee.
15.	CT/144/20 Online Submission (21530) Evenamide	M/s CliniRx	The applicant presented its proposal for protocol amendment 3.0 dated 19.09.2022 before the committee. After detailed deliberation, the committee opined that the applicant should submit approval/acceptance for protocol

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			amendment 2.2 dated 25.08.2021 & protocol amendment 2.4 dated 22.02.2022 along with approval letter/NoC for increase of sample size from 60 to 100 subjects from India for further consideration.
New Drug Division			
16.	ND/MA/20/000078 Pimavanserin Capsules	M/s. Sun Pharma	In light of earlier recommendation dated 16.12.2022, the firm presented its proposal and requested to consider the protocol amendment before the committee. After detailed deliberation, the committee recommended to conduct the Phase III clinical trial as per protocol no. ICR/21/012 version no. 3.0 dated 25.11.2022.