

Recommendations of the SEC (Neurology & Psychiatry) made in its 100th meeting held on 20.12.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/169/22 Online Submission (28582) Varespladib	M/s. Inventiv International Pharma	The firm presented protocol amendment version 4.0 dated 03 August 2023, protocol no. OPX-PR-03. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
2.	CT/132/23 Online Submission (40198) SAR442168/ Tolebrutinib	M/s. Sanofi	The firm presented phase III clinical study protocol no. LTS17043. After detailed deliberation, the committee opined that the firm should submit the following for review by the committee: 1. Modified Informed Consent Form mentioning the details about 11 times visit to the site, volume of sample to be collected and compensation to be paid in case of visit to the site or home visit. 2 Clearance for shipping of samples outside the country, if any. 3. Written assurance for home visit if the patient is unable to visit the site.
3.	CT/143/23 Online Submission (40495) OAV101/ Onasemnogene Abepravovec	M/s. Novartis	The firm did not turn up for presentation
4.	CT/59/21 Online Submission (29386) Ofatumumab (OMB157) Siponimod (BAF312)	M/s. Novartis	The firm did not turn up for presentation
5.	CT/84/20 Online Submission (29323) Inebilizumab	M/s. Medpace Clinical Research India Pvt. Ltd.	The firm did not turn up for presentation