**Recommendations of the SEC (Gastroenterology & Hepatology) made in its 58th meeting held on 16.03.2023 & 17.03.2023 at CDSCO (HQ), New Delhi:**

| S.No. | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| **New Drugs Division** | | | |
| 1. | ND/CT/22/000069<br><br>Vonoprazan fumarate tablets 20 mg | M/s. Centaur Pharma | The firm intended to present phase III CT protocol along with BE study waiver with Vonoprazan fumarate tablets 20mg before the committee.<br>However, the firm has not submitted formally the application for Phase III CT protocol to CDSCO.<br>Therefore after detailed deliberation, the committee recommended that the firm should submit Phase III CT protocol and requisite documents as per New Drugs and Clinical Trial Rules, 2019 for review by this office. |
| 2. | ND/MA/23/000028<br><br>Vonoprazan Tablets 10, 20 mg | M/s Optimus Pharma Pvt. Ltd. | The firm presented the proposal for grant of permission for manufacturing and marketing of the drug Vonoprazan Tablets 10mg/20mg along with Phase III clinical trial protocol and BE study waiver before the committee.<br><br>After detailed deliberation, the committee agreed for waiver of BE study and recommended for grant of permission to conduct the proposed Phase III clinical trial as per the proposed protocol. |
| **Biological Division** | | | |
| 3. | BIO/CT/22/000115<br><br>Ustekinumab Pre-filled syringes 45 mg/0.5 ml, 90 mg/ml and Single use vial 130 mg/ 26 ml | M/s Johnson & Johnson Pvt. Ltd. | The firm presented the protocol to conduct Phase IV clinical trial titled "An Open Label, Multicenter, Phase IV Study of Ustekinumab to evaluate its safety in Indian subjects with Crohn's Disease (CD)" vide protocol CNTO1275CRD4045.<br><br>After detailed deliberation, the committee recommended for approval of the presented Phase IV study protocol. |
| 4. | BIO/CT18/FF/2022/ 35021<br><br>Ustekinumab Pre-filled syringes 45 mg/0.5 ml, 90 mg/ml and Single use vial 130 mg/26 ml | M/s Johnson & Johnson Pvt. Ltd. | The firm did not turn up for the presentation. |

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| **SND Division** | | | |
| 5. | SND/MA/20/000083<br><br>Ursodeoxycholic Acid Tablets IP 150mg/300mg/450mg /600mg | M/s Abbott India Ltd. | The firm presented its proposal for amendment in Phase III clinical trial protocol (No. UDIL3002, version 4, dated 26.07.2022) with respect to inclusion and exclusion criteria like inclusion of the patients with gestational age of ≥ 22 weeks at the time of study enrollment but less than or equal to 35 weeks, instead of inclusion of the patients with gestational age of ≥ 28 weeks at the time of study enrolment but less than or equal to 33 weeks before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as per the amended protocol presented by the firm. |
| **GCT Division** | | | |
| 6. | CT/28/22<br>Online Submission (20917)<br><br>Guselkumab (CNT01959) | M/s. Parexel | The firm presented the proposed protocol amendment version 5.0 dated 12/ JUL/2022 under the Phase 2/3 protocol no. CNTO1959CRD3001 (GALAXI) before the committee.<br><br>After detailed deliberation, the committee recommended for approval of proposed protocol amendment provided that there would be no impact on the already approved no. of subjects in the country due to the proposed amendment and the global endpoints and hypothesis would be followed for India. |
| 7. | CT/142/22<br>Online submission (34813)<br><br>AZD2693 | M/s. Astra Zeneca | The firm presented the proposed trial protocol no. D7830C00004, version 2.0 dated 14-Feb-2023 (FORTUNA) before the committee.<br>After detailed deliberation, the committee recommended for grant of permission for conduct of the study as presented with the following conditions:<br>1) The firm should submit the Phase I study (D7830C00006 & D7830C00002) data along with the safety reports from the current proposed trial to CDSCO and SEC for review as and when available as per the trial protocol. |

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| | | | 2) The firm should submit safety data from other centres across the world for the need of follow up liver biopsy in placebo arm.<br>3) The trial site should have the capacity to do the trial related investigations. |
| 8. | CT/102/22<br>Online Submission (33917)<br><br>Filgotinib [GS-6034, Formerly GLPG0634 | M/s. PRA | The firm presented the proposed protocol version 1.0 dated 04-Apr-2022 for the Phase IIIb protocol no. GLPG0634-CL-341 before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the study as presented. |
| 9. | CT/124/20<br>Online Submission (19890)<br><br>Brazikumab | M/s. Astra Zeneca | The firm presented the proposed protocol amendment 5 version 6.0 dated 07-Dec-2021 for the Phase II protocol no. D5271C00001 (Intrepid Lead-In) before the committee.<br><br>After detailed deliberation, the committee recommended for approval of the proposed protocol amendment. |
| 10. | CT/138/22<br>Online Submission (34729)<br><br>Tegoprazan 50mg Tab. | M/s. Reddy's | The firm presented the protocol to conduct Phase III clinical trial titled "A multi-national, multi-centric, prospective, randomized, double-blind, active-controlled, parallel group study to evaluate the efficacy and safety of Tegoprazan in patients with erosive gastro esophageal reflux disease" vide protocol no. DRL-IND-NDA08-TEG/2022; Version 1.0 dated 28-Oct-2022.<br><br>After detailed deliberation, the committee recommended to revise the protocol with respect to the exclusion criteria number 15 &18 to specify that subject's history of malignancy should be excluded in the study and exclusion of the subject's from the study should be based on their previous medication half-lives or as per discretion of investigator.<br>Accordingly, the firm should submit revised protocol for further review by the committee. |
| 11. | CT/178/22<br>Online Submission (35386) | M/s JSS | The firm presented its proposal for Phase III clinical trial protocol no. CM4620-03, Version 3.0 dated 31-Mar-2022 for the |

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| | Zegocractin | | Phase IIb protocol before the committee.<br><br>After detailed deliberation, the committee recommended for grant permission to conduct the study. |
| 12. | CT/149/22<br>Online Submission (34669)<br><br>Diltiazam Hydrochloride 2% | M/s Cliantha | The firm presented Phase III clinical trial protocol no. C2A01987, protocol version no. 02 dated 21-Sept-2022.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial subject to the condition that concomitant medication/ rescue medication for pain management should be specified in protocol.<br>Accordingly, the firm should submit revised protocol to CDSCO for approval. |
| 13. | CT/164/22<br>Online Submission (35110)<br><br>Ozanimod | M/s PSI | The firm presented the Phase-III clinical trial protocol no. RPC01-3203, protocol version no. 06 dated 14-Jun-2021.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial.<br><br>Dr. Vineet Ahuja did not participate during the deliberation. |
| 14. | CT/139/22<br>Online Submission (34735)<br><br>Guselkumab and Golimumab | M/s Parexel | The firm presented the Phase IIb clinical trial protocol no. 78934804CRD2001, protocol amendment no. 01 dated 14-April-2022.<br><br>After detailed deliberation, the committee recommended that the firm should submit available safety data along with nature of AEs/SAEs from ongoing studies with the investigational product for review by the committee. |
| 15. | CT/140/22<br>Online Submission (34792)<br><br>Guselkumab and Golimumab | M/s Parexel | The firm presented the Phase IIb clinical trial protocol no. 78934804UCO2001, protocol amendment no.01 dated 14-April-2022.<br><br>After detailed deliberation, the committee recommended that firm should submit available safety data along with nature of AEs/SAEs from ongoing studies with the investigational product for review by the committee. |

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| 16. | CT/165/22<br>Online Submission (35116)<br><br>Ozanimod | M/s PSI | The firm presented the Phase III clinical trial protocol no. RPC01-3204, protocol version no. 06 dated 14-Jun-2021.<br>After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial.<br><br>Dr. Vineet Ahuja did not participate during the deliberation. |
| 17. | CT/181/22<br>Online Submission (35431)<br><br>ABX464 | M/s IQVIA | The firm presented the Phase III clinical trial protocol no. ABX464-105, protocol version No.03 dated 06-Oct-2022.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial. |
| 18. | CT/15/17<br>Online Submission (20992)<br><br>Filgotinib | M/s. Klinera | The firm presented the proposed protocol amendment version 9.0 dated 14-April-2022, protocol no. GS-US-418-3899 before the committee.<br><br>After detailed deliberation, the committee did not recommend for approval of the proposed amendment as there is no rationale for dose de-escalation from higher dose 200mg to lower dose 100mg. |
| 19. | CT/73/21<br>Online Submission (19891)<br><br>Brazikumab | M/s AstraZeneca | The firm presented the proposed protocol amendment 4 version 5.0 dated 04 April 2022, protocol no. D5271C0002 before the committee.<br><br>After detailed deliberation, the committee recommended for approval of proposed protocol amendment with condition that Quantiferone TB Gold test (QFT-G) should be done at screening visit and subsequent periodic evaluation of TB should be done for Indian subjects. |
| 20. | CT/74/21<br>Online Submission (19997)<br><br>Brazikumab | M/s AstraZeneca | The firm presented the proposed protocol amendment 3 version 4.0 dated 13-May - 2022, protocol no. D5272C0002 before the committee.<br><br>After detailed deliberation, the committee recommended for approval of the proposed protocol amendment with condition that Quantiferone TB Gold test (QFT-G) should be done at screening visit and subsequent periodic evaluation of TB should be done for Indian subjects. |

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| 21. | CT/158/21<br>Online Submission (21691)<br><br>Mirikizumab | M/s Eli Lilly | The firm presented the proposed protocol amendment I6T-MC-AMAX (b) dated 03-08-2022 and protocol addendum 8.1 dated 14-10-2022 before the committee.<br><br>After detailed deliberation, the committee recommended for approval of the proposed protocol amendment and protocol addendum. |
| 22. | CT/81/17<br>Online Submission (22152)<br><br>Filgotinib | M/s. Klinera | The firm presented the proposed protocol amendment version 6.0 dated 09-Sep-2022 under the Phase II protocol no. GS-US-418-4279 before the committee.<br><br>After detailed deliberation, the committee recommended for approval of the proposed protocol amendment. |
| 23. | CT/157/22<br>Online Submission (35074)<br><br>Ozanimod Tablets | M/s PSI | The firm presented the Phase III clinical trial protocol no. RPC01-3201, protocol version No.06 dated 14-Jun-2021.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial.<br><br>Dr. Vineet Ahuja did not participate during the deliberation. |