

**Recommendations of the SEC (Gastroenterology & Hepatology) made in its 22<sup>nd</sup> meeting held on 10.10.2019 at CDSCO HQ New Delhi:**

| Agenda No                | File Name & Drug Name, Strength   | Firm Name  | Recommendations   |
|--------------------------|---|--|---|
| <b>New Drug Division</b> |   |  |   |
| 1                        | ND/MA/19/000021<br>Obeticholic Acid<br>5mg/10mg Tablets   | M/s Akums<br>Drugs &<br>Pharmaceuticals<br>Limited | The firm presented the proposal along with the BE Protocol before the committee. After detailed deliberation the Committee noted that PBC is a rare disease with a very limited treatment options. The Committee recommended that the approval of the drug with local clinical trial waiver may be considered subject to following condition:- 1. Dosing higher than recommended in the drug label can increase the risk for liver decompensation, liver failure, and sometimes death. Routine monitoring of all patients for biochemical response, tolerability, and PBC progression, and re-evaluation of child-Pugh classification to determine if dosage adjustment is needed, are necessary. The Committee recommended for grant of permission to conduct Bio-equivalence study. The firm should submit the result of BE study along with proposed Package Insert and detailed modalities to be adopted for sale and distribution of the drug addressing the above concerns for review by the committee. |
| 2                        | 12-01/18-DC(Pt-322)<br>An objective evaluation of the effect of Octreotide on pancreatic texture in patients undergoing pancreaticoduodenectomy | Dr.Sharmila<br>Jalgaokar, IEC -<br>I, Mumbai       | The applicant presented the proposal along with the clinical trial protocol before the committee. After detailed deliberation the committee recommended to conduct the study subject to condition that the local ethics committee approval should be obtained before initiating the study.  |
| 3                        | ND/IMP/19/00014/12917<br>Import and Marketing of<br>Esoxx   | M/s Synergy<br>Pharma                              | The firm didn't turn up for the presentation  |
| 4                        | Proton pump inhibitors<br>acute kidney failure  | PvPI   | The committee deliberated the recommendation of the NCC-PvPI. After detailed deliberation the committee recommended that CDSCO to request the State Drugs Controllers to direct the manufacturers of Proton Pump inhibitors to incorporate acute kidney injury as an  |

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|                                     |   |   | adverse drug reaction into the PIL.  |
| <b>Subsequent New Drug Division</b> |   |   |  |
| 5                                   | SND/MA/19/000107<br>Acotiamide HCl hydrate SR 300mg tablet (modified release dosage form) | M/s Synokem Pharmaceuticals Ltd.            | The firm presented their proposal along with BE study protocol before the committee.<br>After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. Clinical Trial protocol may be reviewed after submission of BE study report.   |
| <b>FDC Division</b>                 |   |   |  |
| 6                                   | FDC/MA/19/000015<br>Levosulpiride + Rabeprazole Sodium (75 mg + 40 mg) capsules           | M/s. Akums Drugs & Pharmaceuticals Ltd.     | The firm presented their proposal before the committee.<br>After detailed deliberation, the committee opined that firm has not presented any added advantage of the proposed FDC (capsule dosage form) over approved FDC in tablet dosage form. Therefore, committee reiterated their earlier recommendation dated 24.04.2019.   |
| 7                                   | FDC/IMP/19/000042<br>B.Fluid  | M/s. Otsuka Pharmaceuticals India Pvt. Ltd. | The firm presented their proposal before the committee with request for clinical trial waiver.<br>After detailed deliberation, the committee opined that firm has not presented any relevant data to justify for the clinical trial waiver. Hence committee didn't recommend the Phase III clinical trial waiver. Accordingly, firm should submit Phase III Clinical Trial protocol before the committee.  |
| <b>GCT Division</b>                 |   |   |  |
| 8                                   | CT/46/19<br>CT-P13  | PPD   | In light of recommendation of previous SEC held on 22-08-2019, Applicant presented their response for the including the site before the committee.<br><b>Assessment of risk versus benefit to the patients-</b> The safety profile of the study drug from various preclinical toxicology studies and clinical studies justify the conduct of the trial.<br><b>Innovation vis-a-vis existing therapeutic:</b> To Evaluate the Efficacy and Safety of the Subcutaneous Injection of CT-P13 (CT-P13 SC) as Maintenance Therapy in Patients with Moderately to Severely Active Crohn's Disease.<br><b>Unmet medical need in the country-</b> To develop safe and efficacious alternative |

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|           |                                 |           | <p>treatment in Patients with Moderately to Severely Active Crohn's Disease.</p> <p>After detailed deliberation the committee recommended for grant of permission to conduct the study.</p>   |
| 9         | CT/52/19<br>Etrasimod           | IQVIA     | <p>In light of recommendation of previous held on 22-08-2019. Applicant presented response for the including the site before committee <b>Risk versus benefit to the patient</b></p> <p>The safety profile of the study drug preclinical and clinical studies justify conduct of the trial.</p> <p><b>Innovation vis-a-vis existing therapeutic-</b><br/>The primary objective is to assess the efficacy etrasimod on clinical remission in subjects moderately to severely active ulcerative colitis (UC) after 12 and 52 weeks of treatment.</p> <p><b>Unmet medical need in the country</b><br/>current and projected to assess the efficacy safety of etrasimod in subjects with moderately to severely active ulcerative colitis an unmet medical need.</p> <p>After detailed deliberation the committee recommended for grant of permission to conduct the study.</p> |
| 10        | CT/53/19<br>Etrasimod           | IQVIA     | <p>In light of recommendation of previous held on 22-08-2019. Applicant presented response for the including the site before committee <b>Risk versus benefit to the patient</b></p> <p>The safety profile of the study drug preclinical and clinical studies justify conduct of the trial.</p> <p><b>Innovation vis-a-vis existing therapeutic-</b><br/>The primary objective is to assess the efficacy etrasimod on clinical remission in subjects moderately to severely active ulcerative colitis (UC) after 12 and 52 weeks of treatment.</p> <p><b>Unmet medical need in the country</b><br/>current and projected to assess the efficacy safety of etrasimod in subjects with moderately to severely active ulcerative colitis an unmet medical need.</p> <p>After detailed deliberation the committee recommended for grant of permission to</p>                    |

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|           |                                 |           | conduct the study.  |
| 11        | CT/54/19<br>Etrasimod           | IQVIA     | <p>In light of recommendation of previous held on 22-08-2019. Applicant presented response for the including the site before committee <b>Risk versus benefit to the patient</b>. The safety profile of the study drug from preclinical and clinical studies justify conduct of the trial.</p> <p><b>Innovation vis-a-vis existing therapeutic-</b> The primary objective is to assess the efficacy of etrasimod on clinical remission in subjects with moderately to severely active ulcerative colitis (UC) after 12 and 52 weeks of treatment.</p> <p><b>Unmet medical need in the country</b> current and projected to assess the efficacy and safety of etrasimod in subjects with moderately to severely active ulcerative colitis an unmet medical need. After detailed deliberation the committee recommended for grant of permission to conduct the study.</p>                               |
| 12        | CT/65/19<br>Brazikumab          | Parexel   | <p>The firm presented their proposal before the committee.</p> <p><b>Assessment of risk vs. Benefit to the patients:</b> The safety profile of the study drugs from preclinical toxicology studies including repeat dose toxicity and Phase-I clinical study justify the conduct of the trial.</p> <p><b>Innovation vis-à-vis Existing Therapeutic option:</b> The Purpose of the study is to assess the efficacy of Brazikumab in Patients with Moderately to Severely Active Crohn's disease</p> <p><b>Unmet Medical need in the country:</b> The test drug may potentially provide Treatment in patients with moderately to severely active Crohn's disease.</p> <p>After detailed deliberation the committee recommended for grant of permission to conduct the study. The committee also advised to include investigator sites to have equal representation from government medical colleges</p> |