

Recommendations of the SEC meeting to examine IND proposals, made in its 20th meeting held on 16.02.2022, 12:00 noon at CDSCO, HQ New Delhi, through Webex (Video conference):

| Agenda No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|--------------------------|--|--|---|
| New Drug Division | | | |
| 1. | F. No. IND/CT/22/000003 Intravesical SN-38 Lipid Suspension | M/s Intas Pharma | <p>The firm presented their proposal to conduct Phase II clinical trial along with the protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase II Clinical trial subject to following conditions-</p> <ol style="list-style-type: none"> 1. The study should be termed as Phase I. 2. Inclusion criteria should be modified to include patients who have already been treated with radiotherapy, chemotherapy and surgery. 3. After completion of 1st dose cohort (40mg/50ml), the report should be presented before the committee, for proceeding to the next dose (60mg/50ml). <p>Accordingly, revised protocol should be submitted to CDSCO, before initiation of the study.</p> |
| 2. | F. No. IND/CT/21/000070 HRF 10071 Tablets | M/s Veeda Clinical Research Private Limited | <p>The firm presented their justification for variability in C_{max} before the committee.</p> <p>After detailed deliberation, the committee recommended for continuation of the study.</p> |
| 3. | F. No. 12-02/22-DC (Pt-01) Standardized fraction of Picrorhiza kurroa | Primary Sponsor: CSIR-Central Drug Research | <p>The firm presented their proposal alongwith the Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to</p> |

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| | Royal Ex Benth (Picroliv®) | Institute (CDRI) | <p>conduct the Phase III Clinical trial subject to following conditions-</p> <ol style="list-style-type: none"> 1. The study to be conducted only in Non-alcoholic fatty liver disease (NAFLD) patients in 2:1 ratio (test arm & placebo arm). Accordingly, the title, inclusion and exclusion criteria etc, of the study should be revised. 2. At every three months, investigation for TSH, T3 and T4, HbA1C should be performed. 3. Hepatotoxic drugs should be excluded. 4. Sample size should be recalculated considering the power of the study at 90% confidence Interval. <p>Accordingly, revised protocol should be submitted to CDSCO before initiation of the study.</p> <p>Dr. S.K. Rath, Dr. Manoj Kumar Sharma & Dr. Jerin Jose Cherian didn't participate for this proposal.</p> |

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| 4. | F. No. IND/CT/22/000001 Sovateltide (PMZ 1620) | M/s Pharmazz India Private Limited | <p>The firm presented their Phase II clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended that the firm should submit following justification:</p> <ol style="list-style-type: none"> 1. Data on passage of the drug through the blood brain barrier and brain concentration of drug in animal model. 2. Dose justification as dose proposed in neonates is similar to the adults. 3. Data on receptor and target selectivity of the drug. 4. Details of pharmacokinetics and metabolism of the drug. 5. Safety data of the drug generated till date. 6. Interim report of ongoing clinical trial of the drug. <p>Accordingly, firm should submit the above data/documents to CDSCO for further deliberation, before the committee.</p> |