**Recommendations of the SEC meeting to examine IND proposals, made in its 36th meeting held on 05.06.2023, 12:00 Noon at CDSCO, HQ New Delhi, through Webex (Video Conference):**

| Sr. No. | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| **New Drugs Division** | | | |
| 1. | F. No. IND/CT/23/000041<br><br>Levormeloxifene fumarate Tablets 15mg | M/s Cipla Ltd. | The firm presented its proposal for conduct of Phase I clinical trial Study, "A randomised, single dose, oral, open label, two treatment, parallel pharmacokinetic study between the test product, Levormeloxifene 15 mg tablet and the reference product, Saheli (Ormeloxifene also known as Centchroman) 30 mg tablet administered in healthy adult female subjects under fasting condition" along with in-vitro and in-vivo preclinical data of Ormeloxifene before the committee.<br><br>The committee noted that Ormeloxifene (racemic mixture, i.e., 50% of Levo and 50% of Dextro) is already approved by CDSCO and now the firm has requested for waiver of non-clinical studies for Levormeloxifene which is Levo-form of Ormeloxifene.<br><br>After detailed deliberation, the committee agreed to the firm's request for the waiver of non-clinical studies of Levormeloxifene and recommended for grant of permission to conduct the Phase I Clinical trial as per the presented protocol.<br><br>**Dr. S. K. Rath CSIR-CDRI didn't participate in the deliberation.** |
| 2. | F. No. IND/CT/23/000044<br><br>HRF-10071 Tablet 120mg and Lamivudine | M/s Synapse Labs Pvt. Ltd | The firm presented its proposal for conduct of Phase I clinical trial alongwith preclinical data before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed study as presented by the firm. |

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| 3. | F. No. IND/CT/22/000043<br><br>HRF-10071 Tablet 120mg and Darunavir and Ritonavir | M/s Veeda Clinical Research Ltd. | The firm presented the Phase I Clinical study report to evaluate the Pharmacokinetic interactions between HRF-10071 and Darunavir and Ritonavir before the committee.<br><br>After detailed deliberation, the committee noted the results of the Phase I clinical study & agreed to the firm's request. |
| 4. | F. No. IND/CT/22/000058<br><br>Desidustat Tablets 150mg | M/s Zydus Lifesciences Limited | The firm presented the Phase I Clinical study report to evaluate the comparative pharmacokinetic study of Desidustat 150 mg of M/s. Zydus Lifesciences Ltd, India + Zyrova containing Rosuvastatin Calcium 10 mg of M/s Zydus Healthcare Ltd., India with Zyrova containing Rosuvastatin Calcium 10 mg of M/s Zydus Healthcare Ltd., India in healthy, adult, human subjects under fasting condition before the committee.<br><br>After detailed deliberation, the committee noted the results of the Phase I clinical study & agreed to the firm's request. |
| 5. | F. No. IND/CT/23/000040<br><br>LNP3693 | M/s Lupin Limited | The firm presented its proposal to conduct Phase I clinical trial alongwith in-vitro and in-vivo preclinical data before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission for conduct of the Phase I clinical trial as per the presented protocol subject to the conditions that the chief eligibility criteria should be patients with advanced cancer, with refractory or recurrent disease who have failed at least two lines of therapy and have no further access to curative therapy. |
| 6. | F. No. IND/CT/21/000014<br><br>MKP10241 | M/s Mankind Pharma Limited | The firm presented interim clinical safety report for the IND MKP10241 in Single Ascending Dose (SAD) study (Strength: 200mg, 300mg and 400mg) and requested for approval of further phase I clinical trial of MKP10241 for |

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| | | | Multiple Ascending Dose (MAD) (For Strength: 100mg, 200mg and 400mg) before the committee.<br><br>The committee noted the results in SAD of the phase I clinical study (Strength: 200mg, 300mg and 400mg) & agreed to the firm's request.<br><br>After detailed deliberation, the committee recommended for grant of permission for conduct of Multiple Ascending Dose (MAD) phase I clinical trial (For Strength: 100mg, 200mg and 400mg) as per the protocol presented by the firm. |
| 7. | F. No. IND/CT/22/000056<br><br>HRF-10071 Tablet 120mg and Rifampicin 600mg Capsule. | M/s Synergen Bio Private Limited | The firm presented the Phase I Clinical study report to evaluate the Pharmacokinetic interactions between HRF-10071 and Rifampicin 600mg Capsule before the committee.<br><br>After detailed deliberation, the committee noted the results of the Phase I clinical study & agreed to the firm's request. |
| 8. | F. No. IND/CT/23/000030<br><br>Nuvastatic® 1000 mg sachet containing effervescent powder<br><br>(Standardized extract of Orthosiphonstamineus leaves) | M/s Synergen Bio Pvt. Ltd | In light of earlier SEC (Oncology & Haematology) dated 09.02.2023, the firm presented its proposal to conduct Phase I clinical trial along with the in-vitro and in-vivo preclinical data before the committee.<br><br>After detailed deliberation, the committee noted that the firm's preclinical pharmacokinetic, pharmacological and toxicological data & characterization of minimum four bio-active or phyto-chemical compounds are inadequate for grant of permission to conduct the Phase I Clinical Trial.<br><br>In view of the above, after detailed deliberation, the committee opined that the firm's application cannot be considered for approval and may be rejected. |

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| **Biological Division (r-DNA)** | | | |
| 9. | F. No. BIO/CT/22/000111<br><br>NM8074 | M/s Ablenio Sciences Private Limited | In light of earlier SEC recommendation dated 13.03.2023, the firm presented revised Phase II clinical trial protocol vide protocol no NM8074-aHUS-401 version 2.0 dated 27.04.2023 before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase II clinical trial as per the presented protocol. |