

Recommendations of the SEC meeting to examine IND proposals, made in its 40th meeting held on 29.12.2023, from 11:00 AM to 6:00 PM at CDSCO (HQ), New Delhi, through Webex (Video Conference):

| S.No. | File No., Drug Name & S | Name of Applicant | Recommendations |
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| Investigational New Drugs Division | | | |
| 1 | File No.: IND/CT/23/000088 Drug Name: PNB-001 Capsules 25 mg, 50 mg,100 mg | M/s. Biosphere Clinical Research Pvt. Ltd. | The firm presented the proposal to conduct Phase-II clinical trial titled "A Phase II, Multicenter, Randomized, Double-blind, Placebo controlled clinical study to evaluate the efficacy and safety of PNB-001 in Subjects with Type 2 Diabetes Mellitus., (Protocol No.: BCR-PNB-004 Version No. 1.0, Date 21-SEP-2023). The committee noted that the trial Protocol is for recruitment of 2 groups i.e. T2DM and Nephropathy. After detailed deliberation, the Committee recommended for grant of permission to conduct the Phase II clinical trial only in the T2DM patients and not the 2 nd group i.e. T2DM patients with Nephropathy. The Trial to be conducted in 75 subjects in a ratio of 2:2:1 (Arm A 25mg: Arm B 50 mg: Arm C Placebo with Standard of care, diet, Exercise) in T2DM. Accordingly, the firm to submit the Revised Protocol, IB, ICD and other associated documents to CDSCO for further review by the Committee . |
| 2 | File No.: IND/CT/23/000080 Drug Name: HRF-10071 Tablets 120 mg | M/s Synergen Bio Private Limited. | The firm presented their proposal to conduct the Phase 1 clinical trial titled "A Phase I, Three-treatment, Two-period, Non-randomized, Single sequence, One-way Interaction Study to Evaluate the Pharmacokinetic Interactions between HRF-10071 Tablet 120mg and Clopidogrel 75 mg Tablet under Fasting Conditions" (Protocol No.: HCR/I/HRF10071-CLOP/09/2023 Version No. 01 Date: 26-SEP-2023) After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I trial for drug –drug interaction as per the protocol presented by the firm. |
| 3 | File No.: IND/CT/22/000036 Drug Name: AB001 Tablets 40 mg,100 mg, 200 mg, 400 mg, 500 mg and 800 mg | M/s Vopec Pharmaceuticals Private Limited. (Re- deliberation) | The Recommendations of the 39 th SEC dated 18.10.2023 is as follows: The firm presented the Clinical Study report of Phase I trial with the study drug: titled "A phase 1, open label study to evaluate MTD, safety, tolerability and pharmacokinetics of oral drug AB001 in patients with various types of metastatic cancer patients." After detailed deliberation, the committee recommended that the firm should present the Safety data of the study drug in a stratified manner i.e. in patients with metastatic versus locally advanced solid tumor malignancies disease wise; Safety data of patients of lower age group versus higher age group, disease wise. Safety data of study drug in patients considering concomitant drugs for each type of cancer. The firm is also required to present pharmacokinetic data for each of the patients, dose cohort wise. |

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| | | | Accordingly, the firm presented the data in the 40th SEC. After detailed re-deliberation the committee noted the Phase I trial data presented by the firm. |
| 4 | File No. IND/CT/23/000079 Drug Name: AUR 109 Tablets 100 mg | M/s. Aurigene Oncology Limited. | The firm presented their proposal to conduct Phase II trial titled "A Phase II, Open-label, Randomized, Dose-ranging Study Evaluating the Efficacy, Safety, Pharmacokinetics and Pharmacodynamics of AUR 109 in Patients with Colorectal, Ovarian, and Renal Cancers (TEJAS-2)" (Protocol No.: AUR 109-202 Version No. 2.0 Date 19-SEP-2023). After detailed deliberation, the committee recommended for grant of approval of the Phase II trial as per the protocol presented by the firm with the condition that the clinical trial protocol approved by USFDA and the justification for adequacy of sample size should be submitted. Accordingly, the firm should submit the information to CDSCO. |
| 5 | File No.: IND/CT/22/000027 Drug Name: AUR 103 25 mg and 100 mg capsules | M/s. Aurigene Oncology Limited | The firm presented their proposal for the amendment of approved Phase I trial to Phase I/IIa vide Protocol No. AUR 103-101 Version 5.0: Date: 8 th November 2023. The revised Protocol title is as follows: " A Phase I/IIa, Open Label, Dose-Escalation, First in Human (FIH) study evaluating the Safety, Pharmacokinetics, Pharmacodynamics and Efficacy of AUR103 Calcium in patients with relapsed advanced malignancies (BHARAT-1)" Protocol No. AUR103-101: Version 5.0: Date: 8 th November 2023. The firm presented the Safety data of the Part 1 (Single Dose escalation) of Phase I trial and requested for conduct of the Part 2 of the revised protocol in combination with Azacitidine in Randomized manner. After detailed deliberation, the committee recommended to proceed for conduct of the Part 2A of the study as per the revised Protocol presented by the firm. Accordingly, the firm should submit the data of the Part 2A (Combination Dose Escalation) of the study to CDSCO before proceeding for the Part 2B for further review by the committee. |
| 6 | File No. ND/CT/23/000003 Drug Name: AUR 107 5 mg and 20 mg tablets | M/s. Aurigene Oncology Limited. | The firm presented the Protocol for amendment vide Protocol No. AUR 107-101 Version 3.0: Date: 20-Oct-2023. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I clinical trial as per amended Protocol No. AUR 107-101 Version 3.0: Date: 20-Oct-2023. to enroll patients with multiple myeloma in backfill cohorts. Accordingly, the firm should submit the revised IB,ICF and other associated revised documents to CDSCO. |

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| 7 | F. No. IND/CT/23/000021 Drug Name: AUR 108 10mg and 50mg capsules | M/s. Aurigene Oncology Limited. | The firm received approval for the conduct of the Clinical trial titled: "A Phase I, Open Label, Dose-Escalation, Dose Expansion, Multicenter Study Evaluating the Safety, Pharmacokinetics, Pharmacodynamics of Oral AUR 108 in Patients with Relapsed Advanced Lymphoma (ASHA-1)." (Protocol No.AUR108-101, Version No.: 1.0, Date: 13.03.2023) with the following condition : "The firm should conduct the study with the lower dose and fewer subjects i.e. 50 mg in 03 subjects and present the data before the Committee for further consideration." Accordingly, the firm presented the data of the 1 st cohort of 3 patients and requested permission to proceed for the next cohorts. After detailed deliberation, the committee recommended to proceed for the next cohorts as per the approved Protocol. |
| 8 | File No.: IND/CT/23/000083 Drug Name: Nor-Ursodeoxycholicacid tablets 500 mg | M/s Shilpa Medicare Limited. | The proposal was deferred to next SEC meeting (IND). |
| 9 | File No.: IND/CT/23/000030 Drug Name: Orthosiphon stamineus Effervescent powder (Nuvastatic®) | M/s Synergen Bio Private Limited. (Re-deliberation) | The proposal was deferred to next SEC meeting (IND). |