Clinical Trial Details (PDF Generation Date :- Sun, 24 Mar 2024 14:44:40 GMT)

CTRI Number	CTRI/2022/12/048015 [Registered on: 12/12/2022] - **Trial Registered Prospectively**
Last Modified On	19/09/2023
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group, Multiple Arm Trial
Public Title of Study	Phase 1 clinical trial on Cancer patients
Scientific Title of Study	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.

Secondary IDs if Any

Secondary ID	Identifier
AB001/CT/2022 Ver 01 dated 14.09.2022	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr M G Dinesh
Designation	Additional Director
Affiliation	Vopec Pharmaceuticals Private Limited
Address	B-13, Mogappair Industrial Estate, Mogappair West, Chennai, Tamilnadu, India Chennai TAMIL NADU 600037 India
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Details Contact Person (Scientific Query)

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Name	Dr M G Dinesh
Designation	Additional Director
Affiliation	Vopec Pharmaceuticals Private Limited
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Source of Monetary or Material Support

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> Vopec Pharmaceuticals Private Limited B-13, Mogappair Industrial Estate, Mogappair West, Chennai, Tamilnadu, India - 600037

Primary Sponsor

Primary Sponsor Details	
Name	Vopec Pharmaceuticals Private Limited
Address	B-13, Mogappair Industrial Estate, Mogappair West, Chennai, Tamilnadu, India - 600037
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
DrSuresh Kumar	Erode Cancer center	Department of Oncology Velavan Nagar Perundurai Raod Thindal Erode Tamil nadu 638012 Erode TAMIL NADU	04242910700 sureshonco@gmail.com
DrAnita Ramesh	Saveetha Medical College and Hospital	Departmnet of Oncology Saveetha Nagar, Thandalam, Chennai Chennai TAMIL NADU	04466726618 anitachandra100@hotmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
IEC- Erode Cancer center	Approved	14/12/2022	No
IEC-Saveetha Medical College and Hospital	Approved	05/12/2022	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	18/08/2022

Health Condition / Problems Studied

Health Type	Condition
Patients	Acute lymphoblastic leukemia [ALL]
Patients	Acute myeloblastic leukemia
Patients	Malignant carcinoid tumors
Patients	Malignant neoplasm of pancreas, unspecified

Intervention / Comparator Agent

Type	Name	Details
Intervention	AB001-(1E,4E,6E)-1-(3,5-dimethoxyphenyl)-7-(4-ydroxy3,5-dimethoxyphenyl)hepta1,4,6-trien-3-one	Dose 40 mg Route of administration: Orally Frequency : BID Duration: 14 days
Intervention	AB001-(1E,4E,6E)-1-(3,5-dimethoxyphenyl)-7-(4-ydroxy3,5-	Dose 100 mg Route of administration: Orally Frequency : BID Duration: 14

	dimethoxyphenyl)hepta1,4,6-trien-3-one	days
Intervention	AB001-(1E,4E,6E)-1-(3,5-dimethoxyphenyl)-7-(4-ydroxy3,5-dimethoxyphenyl)hepta1,4,6-trien-3-one	Dose 200 mg Route of administration: Orally Frequency : BID Duration: 14 days
Intervention	AB001-(1E,4E,6E)-1-(3,5-dimethoxyphenyl)-7-(4-ydroxy3,5-dimethoxyphenyl)hepta1,4,6-trien-3-one	Dose 400 mg Route of administration: Orally Frequency : BID Duration: 14 days
Intervention	AB001-(1E,4E,6E)-1-(3,5-dimethoxyphenyl)-7-(4-ydroxy3,5-dimethoxyphenyl)hepta1,4,6-trien-3-one	Dose 500 mg Route of administration: Orally Frequency : BID Duration: 14 days
Intervention	AB001-(1E,4E,6E)-1-(3,5-dimethoxyphenyl)-7-(4-ydroxy3,5-dimethoxyphenyl)hepta1,4,6-trien-3-one	Dose 800 mg Route of administration: Orally Frequency : BID Duration: 14 days
Comparator Agent	NIL	NIL

Inclusion Criteria

Inclusion Criteria	
Age From	20.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	Willing and able to provide voluntary informed consent and able to comply with protocol requirements. 2. Age – 20 to 65 years. 3. Patients with advanced Cancer not amenable to surgical therapy. 4. Patients must have measurable disease on radiological imaging of CT / MRI / PET scan to monitor treatment response. Measurable disease, as defined by RECIST v1.1. 5. Patients Undergoing is allowed to take part in the study. 6. Women of child bearing potential must agree to either use a contraceptive method or to remain abstinent during the treatment period and for at least 3 months after the last dose of study drug. 7. Life expectancy > 24 weeks. 8. Patient should be willing to undergo all treatment related procedures and investigations. 9. Patient should be willing and ready for PET scan, Blood Investigations, PK, ECG and followup. 10. Patient is willing to take and to tolerate cytotoxic drugs. 11. No history of addiction to any recreational drug or drug dependence. 12. Non-smokers and non-alcoholics.

Exclusion Criteria

Exclusion Criteria	
Details	1. Patients above 65 years of age. 2. Pregnant or lactating women, or intending to become pregnant during the study. 3. Life threatening comorbidities such as HIV, HPV, HBV, HCV, Tuberculosis, CHF, Impaired Hepatic or Renal Function or any psychological deficits etc. 4. Known CNS disease (Alzheimer’s disease, Parkinson’s disease, Bell’s palsy, Cerebral Palsy, Epilepsy, Motor Neuron disease (MND), Multiple Sclerosis (MS), Neurofibromatosis. Sciatica and Shingles) except for treated asymptomatic CNS metastases. 5. Uncontrolled pleural effusion, pericardial effusion, or as cites. 6. Uncontrolled tumor-related pain.

	7. Significant cardiovascular disease, such as New York Heart Association of classification (NYHA) cardiac disease (Class II or greater), MI within 3 months prior to randomization, unstable arrhythmias, or unstable angina. 8. Major surgical procedure within 4 weeks prior to randomization or anticipation of the need for a major surgical procedure during the study other than for diagnosis. 9. History of autoimmune disease. 10. Prior allogeneic stem cell or solid organ transplantation. 11. Poor peripheral venous access. 12. Any other medical condition or uncontrolled systemic disease (e.g. cardiovascular disease, hypertension, diabetes mellitus etc.) that, in the opinion of the Investigator, may make it undesirable for the patient to participate in the study including but not limited to cirrhosis or psychiatric illness/social situations that would limit adherence to study requirements. 13. Patients not suitable for study as per investigators opinion
Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
To assess the safety and toxicity profile of AB001 in patients with metastasis cancer using the NCI CTCAE V4.03, and determine the maximum tolerated dose (MTD). 1. To determine the maximum tolerated dose (MTD) of AB001. 2. To determine the dose limiting toxicities (DLT) of AB001. 3. To establish a safe dose level of AB001 that can be used for future studies.	Day 0 to Day 14

Secondary Outcome

Outcome	Timepoints
1. The pharmacokinetics of AB001 in humans. 2. Observe for evidence of antitumor activity following administration of AB001. 3. If AB001 induces changes in the biomarker in peripheral blood lymphocytes. 4. If there is a pharmacodynamic relationship between the plasma / blood concentrations of AB001 and a clinical or cellular effect. 5. To monitor the tumor reduction & adverse events and to ensure the safety of patients	Day 0 to Day 14 Safety follow up evaluation : on 21st day

Target Sample Size	**Total Sample Size=**36 **Sample Size from India=**36 **Final Enrollment numbers achieved (Total)=**33 **Final Enrollment numbers achieved (India)=**33
Phase of Trial	Phase 1
Date of First Enrollment (India)	12/12/2022
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of	**Years=**0

Trial	**Months=**1 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	NIL
Brief Summary	The identified lead AB001 demonstrated a good solubility and an acceptable in vivo PK profile. The identified AB001 showed an in vivo efficacy in mouse triple-negative breast cancer, Acute myeloid leukemia model, Pancreatic cancer model with a TGI (tumor growth inhibition) of 90% without any mortality growth inhibition in comparison to reported leads. Our results show that AB001 is widely scattered across different organs, but it is preferentially internalized by the tumor both in vitro and in vivo. AB001 administration showed a potent in vivo anticancer activity in xenograft mouse models, and the drug accumulated dramatically and preferentially in the tumor. The follow-up studies for 12 months shows there is no relapse of tumor growth in the internal organs. We demonstrate the effectiveness of AB001 in resensitizing Multiple Drug Resistance breast cancer cells to their original treatment and provide evidence that AB001 may function through a mechanism involving post-translational histone modifications via an indirect histone deacetylase inhibitor (HDACi) activity and selectively target cancer stem cells and induces apoptosis via caspase activity. According to the results, further well-designed clinical studies with dose optimization are now required to stratify the role of this supplement in current Breast Cancer regimens. Our data, together with the apoptotic action of the AB001 on cancer cells, support a rather selective action of AB001 in cancer treatment. According to the results, further well-designed clinical studies with dose optimization are now required to stratify the role of this supplement in current Cancer regimens