Clinical Trial Details (PDF Generation Date :- Wed, 07 Jun 2023 17:37:50 GMT)

CTRI Number	CTRI/2019/09/021256 [Registered on: 16/09/2019] - **Trial Registered Prospectively**
Last Modified On	23/09/2022
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Biological
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	A clinical trial to study the safety and efficacy of biosimilar cetuximab in patients with recurrent locoregional or metastatic squamous cell carcinoma of the head and neck.
Scientific Title of Study	A prospective, multicenter, randomized, double blind, parallel group study to compare the efficacy and safety of biosimilar cetuximab versus innovator cetuximab in combination with platinum-based chemotherapy in patients with recurrent locoregional or metastatic squamous cell carcinoma of the head and neck (SCCHN).

Secondary IDs if Any

Secondary ID	Identifier
ALK18/ENZ124-CET1; v_02 Date: 27-Mar-2019	Protocol Number

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

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Source of Monetary or Material Support

Source of Monetary or Material Support
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> Enzene Biosciences Limited, Plot No. 165/1/26, Block T, Bhosari MIDC Area, Pune-411057, Maharashtra

Primary Sponsor

Primary Sponsor Details	
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Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

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List of Countries
India

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Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
DMH Institutional Ethics Committee	Approved	06/03/2020	No
Ethics Committee, Unique Hospital-Multispecialty & Research Institute	Approved	06/07/2019	No
HCG Manavata Clinical Research Institutional Ethics Committee	Approved	26/06/2019	No
HCG Mulitispeciality Ethics Committee, Ahmadabad	Approved	14/10/2019	No
Health Point Hospital Ethics Committee	Approved	30/09/2019	No
Human Ethics Committee, Trivandrum	Submittted/Under Review	No Date Specified	No
Institute Ethics Committee, All India Institute of Medical Sciences, Delhi	Approved	20/12/2019	No
Institutional Ethics Committee of Aayush Hospital	Approved	20/02/2021	No
Institutional Ethics Committee, AIIMS Bhubaneshwar	Approved	13/01/2020	No
Institutional Ethics Committee, Amrita Institute of Medical Sciences, Kochi	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee, Government Medical College	Approved	01/08/2019	No
Institutional Ethics	Approved	01/07/2020	No

Committee, JIPMER, Puducherry			
Institutional Ethics Committee, Kerala	Approved	18/12/2019	No
Institutional Ethics Committee, King George Hospital	Approved	05/04/2021	No
Institutional Ethics committee, Mahatma Gandhi Medical College and Hospital	Approved	27/05/2021	No
Institutional Ethics Committee, Omega Hospitals	Approved	19/02/2021	No
Institutional Ethics Committee, PGIMER, Chandigarh	Approved	28/04/2020	No
Institutional Ethics Committee, RST Regional Cancer Center, Nagpur	Approved	20/07/2020	No
Institutional Ethics Committee, TATA Medical Center, Kolkata	Approved	24/03/2020	No
Institutional Ethics Committee, TATA Memorial Hospital	Approved	18/10/2019	No
KEM Hospital Research Centre Ethics Committee	Approved	05/08/2020	No
KLES Dr. Prabhakar Kore Hospital & M.R.C., IEC	Approved	12/11/2019	No
Kolhapur Cancer Centre Institutional Ethics Committee	Approved	02/01/2020	No
Meenakshi Mession Hospital, IEC	Approved	03/03/2020	No
MNJ Institute of Oncology & Regional Cancer Centre Ethics Committee	Approved	30/09/2019	No
Mumbai Oncocare Centre Institutional Ethics Committee	Approved	13/07/2021	No
Mysore Medical college and Research Institute and K.R. Hospital	Approved	25/01/2020	No
Nirmal Hospital Ethics Committee	Approved	05/07/2021	No
SMS medical college, IEC	Approved	19/11/2019	No
Sri Narsimha Saraswati Medical Foundation Ethics Committee	Approved	14/06/2019	No
Sudhbhawana Hospital,	Approved	27/07/2019	No

IEC			

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	24/03/2019

Health Condition / Problems Studied

Health Type	Condition
Patients	Malignant neoplasm of overlappingsites of lip, oral cavity and pharynx

Intervention / Comparator Agent

Type	Name	Details
Comparator Agent	Innovator Cetuximab	Dosage Form: It will be supplied in concentration of 5 mg/mL as a 100 mg/20 ml single-use vial, as a sterile, injectable liquid containing no preservatives. Dosage: The initial dose is 400 mg per m2 to be administered as an IV infusion over a period of 120 mins, subsequently Cetuximab shall be administered at a dose of 250 mg per m2 per week(Cycle 2 to Cycle 18) as an IV infusion over a period of 60 minutes.
Intervention	Biosimilar Cetuximab	Dosage Form: It will be supplied in concentration of 5 mg/mL as a 100 mg/20 ml single-use vial, as a sterile, injectable liquid containing no preservatives. Dosage: The initial dose is 400 mg per m2 to be administered as an IV infusion over a period of 120 mins, subsequently Cetuximab shall be administered at a dose of 250 mg per m2 per week(visit 2 to visit18) as an IV infusion over a period of 60 minute

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	1.Patients of 18-65 years of age at the time of signing the ICF 2.Has life expectancy of at least 6 months from screening 3. Histologically confirmed diagnosis of SCCHN 4. Presence of recurrent locoregional (not suitable for local therapy) or metastatic disease as per Tumor Node Metastasis staging at screening 5. In case of recurrent locoregional carcinoma, patients must have documented progression of platinum-based chemotherapy for recurrent disease 6. Has at least 1 measurable target lesion (tumor/lymph node) as per RECIST version 1.1 at screening 7. Eastern cooperative oncology group (ECOG) status 0 to 2 at screening 8. Willing and able to comply with the protocol 9. Willing to provide written informed consent

Exclusion Criteria

Exclusion Criteria	
Details	1.Patients with Nasopharyngeal cancer 2.Prior systemic chemotherapy (except if given as part of a multimodal treatment for locally advanced disease which was completed more than 6 months prior to screening)

	3.Patient who has received cetuximab or other EGFR targeting agent treatment (except if given as part of a multimodal treatment for locally advanced disease which was completed more than 6 months prior to screening) 4.Surgery (other than minor interventions like diagnostic biopsy or intravenous port implantation) or irradiation within 30 days before randomization 5.Concomitant anti-tumor therapy or concomitant immunotherapy 6.Known sensitivity to any component of the investigational product (IP) and medication used in this study 7.Clinical evidence of brain metastasis or leptomeningeal involvement 8.History of Interstitial Lung Disease 9.History of severe (Grade 3 or 4) allergic or hypersensitivity reaction to therapeutic antibodies 10.Patient's having the following laboratory results at screening a.Absolute neutrophil count (ANC) b.Hemoglobin (Hb) c.Total Leucocyte count d.Platelet count e.Total bilirubin level > 1.5 times the upper limit of the normal laboratory range (ULN) f. Alanine aminotransferase (ALT)/aspartate aminotransferase (AST) levels ? 5 times ULN g.Serum Creatinine level > 1.5 times ULN h.Abnormal serum electrolytes (within normal limit) i. INR and aPTT (within normal limit) 11.Patients suffering from acute or chronic infection(s) 12.Myocardial infarction within 6 months prior to screening 13.Symptomatic congestive heart failure (New York Heart Association [NYHA] Grade 3 or 4), unstable angina pectoris within 6 months prior to screening, significant cardiac arrhythmia, history of stroke or transient ischemic attack within 1 year prior to screening 14. Pre-existing grade 2 or greater motor or sensory neuropathy 15. Active hemoptysis (defined as bright red blood of ½ teaspoon or more in saliva) within 30 days prior to randomisation. 16.History of clinically significant gastrointestinal bleeding (bleeding requiring procedural intervention (e.g., variceal banding, transjugular intrahepatic portosystemic shunt procedure, arterial embolization, topical coagulation therapy) within 6 months prior to randomisation. 17.Patients with history of keratitis 18.Positive serology for human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV) at screening 19.Female patients of childbearing potential not willing to implement adequate non-hormonal contraceptive measures during the study period 20.Patients who are pregnant or nursing 21.Has any concurrent disease or condition, which in the opinion of the investigator does not allow participation of the patient in this study 22.Has participated in any other clinical trial and received experimental medications within 4 weeks prior to screening.

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Centralized
Blinding/Masking	Participant, Investigator, Outcome Assessor and Date-entry Operator Blinded

Primary Outcome

Outcome	Timepoints
1. To compare the efficacy of biosimilar cetuximab versus innovator cetuximab in patients with recurrent locoregional or metastatic SCCHN by assessment of Disease Control Rate (DCR)	1. All patients completed 12 week of treatment 2. All patients completed 18 weeks of treatment

	2.To compare the efficacy of biosimilar cetuximab versus innovator cetuximab in patients with recurrent locoregional or metastatic SCCHN by assessment of overall response rate (ORR)

Secondary Outcome

Outcome	Timepoints
1. Pharmacokinetics (PK) of biosimilar versus innovator cetuximab 2.Immunogenicity of biosimilar cetuximab and innovator cetuximab by assessment of anti-cetuximab antibody (ADA)	Anti-cetuximab antibody (ADA): baseline and Week 18 visit PK Assessment:Baseline, Week2,3 and 4

Target Sample Size	**Total Sample Size=**180 **Sample Size from India=**180 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	Phase 3
Date of First Enrollment (India)	30/10/2019
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Closed to Recruitment of Participants
Publication Details	NIL
Brief Summary	The primary and secondary purpose behind conducting this trial are: 1. To compare the efficacy of biosimilar cetuximab versus innovator cetuximab in patients with recurrent locoregional or metastatic SCCHN by assessment of Disease Control Rate (DCR) and Overall Control Rate (ORR) 2. To compare Pharmacokinetics (PK) of biosimilar versus innovator cetuximab, immunogenicity of biosimilar cetuximab and innovator cetuximab by assessment of anti-cetuximab antibody, safety and tolerability of the investigational product.