Clinical Trial Details (PDF Generation Date :- Thu, 12 Dec 2019 01:23:55 GMT)

CTRI Number	CTRI/2014/09/004980 [Registered on: 05/09/2014] - **Trial Registered Retrospectively**
Last Modified On	04/09/2014
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Other
Public Title of Study	study of combination of Radiation treatment and chemotherapy in advanced Cancer of Head & Neck.
Scientific Title of Study	An Open label, Randomized, Investigator Initiated Multicentric, Phase III Study of Nimotuzumab in combination with Concurrent Radiotherapy and Cisplatin versus Radiotherapy and Cisplatin alone, in Subjects with Locally advanced Squamous Cell Carcinoma of the Head and Neck (LASCCHN)

Secondary IDs if Any

Secondary ID	Identifier
Nil	NIL

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

Details of Principal Investigator	
Name	Dr Kumar prabhash
Designation	Professor and medical oncologist
Affiliation	Tata memorial hospital
Address	Tata Memorial Hospital Dr E Borges Road Parel Mumbai Tata Memorial Hospital Dr E Borges Road Parel Mumbai Mumbai MAHARASHTRA 400012 India
Phone	9167760576
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Details Contact Person (Scientific Query)

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Source of Monetary or Material Support

Source of Monetary or Material Support
> Biocon Limited

Primary Sponsor

Primary Sponsor Details	
Name	Biocon Limited
Address	Tower 2 Ground floor, Semicon park, Electronics city phase 2 Banglore,- 560100 India
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
Not Applicable	Not applicable

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Kumar Prabhash	Tata Memorial Hospital	Tata Memorial Hospital HBB block, 2 nd floor Room no 204, Dr E Borges Road Parel, Mumbai-400012 Mumbai MAHARASHTRA	09167760576 022-24171734 kprabhash1@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee	Approved	09/05/2011	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Patients of Advanced stage Head and Neck carcinoma. having Squamous cell carcinoma.

Intervention / Comparator Agent

Type	Name	Details
Intervention	Chemo Radiation and Nimotuzumab	It is standard of care and cisplatin + Radiotherapy regimen. BIOMAb-EGFR® (Nimotuzumab) will be administered irrespective of any delay or modification in the chemotherapy regimen at weekly intervals starting from V2. Premedication is not indicated. Patients will receive chemotherapy: Cisplatin –30 mg /m2 will be administered as IV infusion weekly once for 7 weeks and radiotherapy: (2Gy daily for 5 days a week) Total 66-70 Gy over a period of 6.5-7 weeks
Comparator Agent	Chemo Radiation	This is standard of care Cisplatin –30 mg /m2 will be

		administered as IV infusion weekly once for 7 weeks and radiotherapy: (2Gy daily for 5 days a week) Total 66-70 Gy over a period of 6.5-7 weeks

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	90.00 Year(s)
Gender	Both
Details	1. Histologically confirmed Squamous Cell Carcinoma of Head and Neck in advanced stage [stage III or IVA ,B)] considered to be suitable for concurrent chemoradiotherapy. 2. Written informed consent has been obtained 3. Karnofsky Performance Status (KPS) > 70 4. Adults of either sex, between 18 years and above with a life expectancy of at least 6 months. 5. Adequate hematologic function (Absolute Neutrophil Count (ANC) ? 1,500 cells/µL; Hemoglobin > 9 g/dL, platelets > 100,000/µL and ? 500,000/µL) 6. Adequate renal function (serum creatinine ? 1.5 mg/dL or calculated creatinine clearance ? 45 ml/min) 7. Adequate hepatic function [bilirubin ? 1.5 x ULN (upper limit of normal), alanine amino transferase (ALT) ? 5 x ULN, aspartate amino transferase (AST) ? 5 x ULN] 8. Female patients must have a negative urine pregnancy test at pre-study (not applicable to patients with bilateral oophorectomy and/or hysterectomy or to those patients who are postmenopausal) 9. All patients of reproductive potential must agree to use an approved form of contraception

Exclusion Criteria

Exclusion Criteria	
Details	1. Nasopharyngeal, salivary glands, nasal cavities, maxillary sinus, paranasal sinus squamous cell carcinoma 2. Patients with a history of prior malignancy other than non-melanoma skin cancer or cervical cancer in-situ 3. Patients who have had immunotherapy 4. Patients who have received radiotherapy to head & neck 5. Known or suspected hypersensitivity to compounds with similarity to BIOMAb EGFR for eg. trastuzumab. 6. Patients with distant metastases 7. Pregnant or lactating women 8. Uncontrolled intercurrent disease (e.g., diabetes, hypertension, thyroid disease) 9. Known infection with HIV or Active viral hepatitis 10. Prior therapy that specifically and directly targets the EGFR pathway

Method of Generating Random Sequence	Stratified block randomization
Method of Concealment	Other
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
To determine the Progression Free Survival to a combination of intravenous BIOMAb-EGFR® (Nimotuzumab), cisplatin and radiotherapy in	At the end of the study

	subjects with advanced [Stage III or IVA, B], histologically documented SCCHN.

Secondary Outcome

Outcome	Timepoints
1. Locoregional Response at 24 weeks from visit of randomization (V2) 2. Locoregional Control 3. Overall Survival, 4. Assessment of quality of life by filling EORTC questionnaire	1. Locoregional response at 24 weeks from Randomization 2. Locoregional control at 2 years 3. Overall survival at points of Interim analysis 3.5 years and at 5 years 4. QOL Assessment at every visit.

Target Sample Size	**Total Sample Size=**536 **Sample Size from India=**536 **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)	05/10/2012
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**5 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	
Brief Summary	Treatment: Total n$_{umbe}$r of 536 subjects will be randomized in ratio of 1:1 (Arm I : Arm II) to receive the treatment as follows: Group I – Total 268 subjects will receive: Nimotuzumab (200 mg/dose, once a week for 7 weeks) + Chemotherapy (cisplatin-30 mg/m^2 dose, once a week for 7 weeks) + Radiotherapy (Total dose of 66Gy to 70Gy in fractions of 2 Gy /day for 5 days/week over 6.5 to 7weeks). Group II – Total 268 subjects will receive: Chemotherapy (cisplatin-30 mg/m^2 dose, once a week for 7 weeks) + Radiotherapy (Total dose of 66Gy to 70Gy in fractions of 2 Gy /day for 5 days/week over 6.5 to 7weeks).

BIOMAb-EGFR®(Nimotuzumab),,chemotherapy & radiotherapy **Doses:**

- Nimotuzumab- 200 mg/dose will be administered as IV infusion weekly once, for 7 weeks.
- Chemotherapy: Cisplatin –30 mg /m^2 will be administered as IV infusion weekly once for 7 weeks.

Radiotherapy: (2Gy daily for 5 days a week) Total 66-70 Gy over a period of 6.5-7 weeks.

Treatment Plan:

Concomitant phase (7 weeks):

Subjects randomized to Group I (study drug arm) will receive BIOMAb-EGFR® (Nimotuzumab) (200 mg/dose once a week) for 7 weeks. Premedication is not indicated for

BIOMAb-EGFR® (Nimotuzumab)., Patients will receive chemotherapy: Cisplatin –30 mg

/m^2 will be administered as IV infusion weekly once for 7 weeks.

Radiotherapy: (2Gy daily for 5 days a week) Total 66-70 Gy over a period of 6.5-7 weeks.

Patients will not be allowed to receive any other anticancer drugs, including immunotherapy, while in the study. Those who require other chemotherapy options will be withdrawn from the study. Growth factor support, antiemetics, and therapy for sensory neuropathies are permitted at investigator’s discretion. Prophylactic growth factor support from cycle 1 is not permitted.

Follow up Phase:

Patient will be evaluated for tumor progression using CT/MRI every six months till 2 years from V2 and every 6 months clinically after 2 years till the end of study.