



Clinical Trial Details (PDF Generation Date :- Wed, 07 Jun 2023 16:54:48 GMT)

<b>CTRI Number</b>	CTRI/2010/091/000170 [Registered on: 24/02/2011] -		
<b>Last Modified On</b>	24/02/2013		
<b>Post Graduate Thesis</b>	No		
<b>Type of Trial</b>	Observational		
<b>Type of Study</b>	Observational PMS		
<b>Study Design</b>	Single Arm Study		
<b>Public Title of Study</b>	An Observational Study to evaluate the safety and efficacy of Cetuximab in combination with platinum-based chemotherapy, in the first-line therapy of recurrent/ metastatic Squamous Cell Carcinoma of Head and Neck (SCCHN)		
<b>Scientific Title of Study</b>	An Observational Study to evaluate the safety and efficacy of Cetuximab in combination with platinum-based chemotherapy, in the first-line therapy of recurrent/ metastatic Squamous Cell Carcinoma of Head and Neck (SCCHN)		
<b>Secondary IDs if Any</b>	<b>Secondary ID</b>	<b>Identifier</b>	
	EMR 62202-514	Protocol Number	
	NCT01142869	ClinicalTrials.gov	
<b>Details of Principal Investigator or overall Trial Coordinator (multi-center study)</b>	<b>Details of Principal Investigator</b>		
	<b>Name</b>	Dr SH Advani	
	<b>Designation</b>		
	<b>Affiliation</b>		
	<b>Address</b>	SL Raheja Hospital Mahim West Mumbai MAHARASHTRA 400016 India	
	<b>Phone</b>	02266529999	
	<b>Fax</b>		
	<b>Email</b>	shadvani2000@yahoo.com	
	<b>Details Contact Person (Scientific Query)</b>	<b>Details Contact Person (Scientific Query)</b>	
		<b>Name</b>	Dr. Rajiv Rana
<b>Designation</b>			
<b>Affiliation</b>		Merck Limited	
<b>Address</b>		5th Floor Shiv Sagar Estate Dr. Anie Besant Road, Worli Mumbai MAHARASHTRA 400018 India	
<b>Phone</b>		+91-22-6669117	
<b>Fax</b>		+91-22-24936046	
<b>Email</b>		rajiv.rana@merck.co.in	
<b>Details Contact Person (Public Query)</b>		<b>Details Contact Person (Public Query)</b>	
	<b>Name</b>	Dr. Sudipto Chatterjee	
	<b>Designation</b>		
	<b>Affiliation</b>		
	<b>Address</b>	5th Floor Shiv Sagar Estate Dr. Anie Besant Road, Worli Mumbai MAHARASHTRA 400018 India	



<b>Phone</b>	+91-22-66609056
<b>Fax</b>	+91-22-24936046
<b>Email</b>	sudipto.chatterjee@merck.co.in

**Source of Monetary or Material Support**

Source of Monetary or Material Support	
> Merck Specialities Pvt Ltd	

**Primary Sponsor**

Primary Sponsor Details	
<b>Name</b>	Merck Specialities Pvt Ltd 5th Floor Shiv Sagar Estate, Dr. Aniee Besant Road, Worli Mumbai 400018
<b>Address</b>	
<b>Type of Sponsor</b>	

**Details of Secondary Sponsor**

Name	Address
NIL	

**Countries of Recruitment**

List of Countries
India

**Sites of Study**

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr. S. M. Karandikar	2, Sweta corner, 7th Lane, Prabhat road, 38/19, Erandwane, Pune-411004, Maharashtra	,- Not Applicable N/A	91-9890281963  skaran44@gmail.com
Dr. M. C. Kar	B.R.Singh Railway Hospital	,- Not Applicable N/A	91-9830155915  madhuchandakar@yahoo.com
Dr. Naresh Somani	Bhagwan Mahavir Cancer Institute	,- Not Applicable N/A	0141-2700107  drsomani@somexresearch.com
Dr Boman Dhabhar	BND ONCO CENTRE	BND ONCO CENTRE, 808, Boman Lodge, Dr. Ambedkar Road, Dadar TT, Dadar (East), Mumbai, India. MAHARASHTRA	9820344570  drboman@hotmail.com
Dr. Jaydip Biswas	Chittaranjan National Cancer Institute	,- Kolkata WEST BENGAL	91-9830026696  drjbiswas.cnci@gmail.com
Dr NVS Ramakrishna	Dr. NVS Ramakrishnas Clinic	5-9-22/8/A, Adarsh Nagar, Near Birla Mandir, Hyderabad-500063 Hyderabad ANDHRA PRADESH	9949341112  rnalla@gmail.com
Dr. Shailesh Puntambekar	Galaxy Care Laproscopic Institute	,- Not Applicable N/A	shase63@gmail.com
Dr. Atul Sharma	Institute Rotary Cancer Hospital	,- Not Applicable N/A	91-9818548149  atul1@hotmail.com
Dr Sharad Singh	J.K.Cancer Institute	,- Not Applicable	91-9452062985



		N/A	sharad_onco@yahoo.co.in
Dr. Ashok Vaid	Medanta The Medicity	,- Not Applicable N/A	91-9810212235 akvaid@yahoo.com
Dr. K. C. Mishra	Meherbai Tata Memorial Hospital	,- Not Applicable N/A	91-99939630090 mishrakc1960@gmail.com
Dr. D. K. Parida	North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences	,- Not Applicable N/A	94361-14334 dkparida@hotmail.com
Dr, Satya Palanki Dattatreya	Omega Hospital	,- Hyderabad ANDHRA PRADESH	91-9440591396 satya_palanki@rediffmail.com
Dr. Arundhati Charaborty	Palliative Care Specialists Unit	,- Kolkata WEST BENGAL	91-9831742166 arundhatic@rediffmail.com
Dr. Minish Jain	Ruby Hall Clinic	,- Pune MAHARASHTRA	91-9823133390 minishjain009@gmail.com
Dr. D. P. Singh	SMS Hospital	,- Jaipur RAJASTHAN	094142-63400 drdpsingh@yahoo.com
Dr. Ghanshyam Biswas	Sparsh Hospital and Critical Care P Ltd	,- Not Applicable N/A	919937500878 drgbiswas@yahoo.com
Dr.Thomas Varughese	The Cancer Clinic	,- Not Applicable N/A	

**Details of Ethics Committee**

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Care Ethics Committee	Approved	No Date Specified	Not Available
Medanta Institutional Review Board	Approved	No Date Specified	Not Available

**Regulatory Clearance Status from DCGI**

Status	Date
Not Applicable	No Date Specified

**Health Condition / Problems Studied**

Health Type	Condition
	Recurrent/ Metastatic Squamous Cell Carcinoma of Head and Neck (SCCHN)

**Intervention / Comparator Agent**

Type	Name	Details
Intervention	Cetuximab in combination Platinum based Chemotherapy	The initial dose is 400 mg per m <sup>2</sup> body surface area (BSA). The subsequent weekly doses are 250 mg/m <sup>2</sup> each. For the initial dose, the recommended infusion period is 120 minutes. For the subsequent weekly doses, the recommended infusion period is 60 minutes. Treatment is to be continued till



		disease progression or DLT
Comparator Agent	NIL	NIL
<b>Inclusion Criteria</b>	<b>Inclusion Criteria</b>	
	<b>Age From</b>	18.00 Year(s)
	<b>Age To</b>	65.00 Year(s)
	<b>Gender</b>	Both
	<b>Details</b>	The study inclusion criteria is as per the local SPC: ?Cetuximab is indicated for the treatment of patients with squamous cell cancer of the head and neck in combination with platinum-based chemotherapy for recurrent and/or metastatic disease.?  For each platinum-based chemotherapy, the related product labels approved by India Health Authorities should also be followed strictly in terms of patient eligibility.
<b>Exclusion Criteria</b>	<b>Exclusion Criteria</b>	
	<b>Details</b>	Patients with known severe (grade 3 or 4; NCI-CTC) hypersensitivity reactions to Cetuximab are contraindicated for Cetuximab
<b>Method of Generating Random Sequence</b>	Not Applicable	
<b>Method of Concealment</b>	Not Applicable	
<b>Blinding/Masking</b>	Not Applicable	
<b>Primary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	Safety and tolerability evaluated based on the incidence and severity of adverse events	At the end of study
<b>Secondary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	1.Response rate 2.Disease Control Rate (DCR) 3. Progression Free Survival (PS) 4.Overall Survival (OS)	At the end of the study
<b>Target Sample Size</b>	<b>Total Sample Size=100</b> <b>Sample Size from India=100</b> <b>Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials</b> <b>Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials</b>	
<b>Phase of Trial</b>	Phase 4	
<b>Date of First Enrollment (India)</b>	No Date Specified	
<b>Date of First Enrollment (Global)</b>	27/10/2009	
<b>Estimated Duration of Trial</b>	<b>Years=2</b> <b>Months=0</b> <b>Days=0</b>	
<b>Recruitment Status of Trial (Global)</b>	Open to Recruitment	
<b>Recruitment Status of Trial (India)</b>		
<b>Publication Details</b>		
<b>Brief Summary</b>	This is a Phase IV Observational study in recurrent and or metastatic Squamous Cell Carcinoma of Head & Neck. The study involves treatment with Cetuximab in combination with Platinum based Chemotherapy in this subset of patients. It is a prospective study wherein safety and efficacy data would be collected over a duration of 2 years from initiation of therapy	