Clinical Trial Details (PDF Generation Date :- Sun, 06 Dec 2020 00:19:44 GMT)

CTRI Number	CTRI/2019/08/020833 [Registered on: 21/08/2019] - **Trial Registered Prospectively**
Last Modified On	01/06/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	Capivasertib plus Paclitaxel as First line Treatment for Locally Advanced (Inoperable) or Metastatic Triple Negative Breast Cancer (CAPItello290)
Scientific Title of Study	A Phase III Double blind Randomised Study Assessing the Efficacy and Safety of Capivasertib plus Paclitaxel Versus Placebo plus Paclitaxel as First line Treatment for Patients with Histologically Confirmed, Locally Advanced (Inoperable) or Metastatic Triple-Negative Breast Cancer (TNBC)

Secondary IDs if Any

Secondary ID	Identifier
D3614C00001_Protocol Version 3.0 dated 12 Nov 2019	Protocol Number
NCT03997123	ClinicalTrials.gov

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

Details of Principal Investigator	
Name	
Designation	
Affiliation	
Address	
Phone	
Fax	
Email	

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Tapankumar M Shah
Designation	Country Director, Clinical Operations
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Details Contact Person (Public Query)

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Source of Monetary or Material Support

Source of Monetary or Material Support
> AstraZeneca AB, 151 85 Sodertalje, Sweden

Primary Sponsor

Primary Sponsor Details	
Name	AstraZeneca AB
Address	151 85 Sodertalje, Sweden
Type of Sponsor	Pharmaceutical industry-Global

Details of Secondary Sponsor

Name	Address
AstraZeneca Pharma India Ltd	Block N1, 12th Floor, Manyata Embassy Business Park Rachenahalli, Outer Ring Road, Bangalore – 560045

Countries of Recruitment

List of Countries
Argentina
Brazil
Canada
Czech Republic
France
India
Japan
Philippines
Poland
Republic of Korea
Russian Federation
Saudi Arabia
Spain
Sweden
Taiwan
Turkey
United Kingdom
United States of America

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
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Dr Joydeep Ghosh	Tata Medical Center	Dept of Medical Oncology, Consultant	03366057000 03366057635

		Medical Oncologist 14 Major Arterial Road EW, Newtown, Rajarhat PIN 700160 Kolkata WEST BENGAL	joydeep.ghosh@tmckolkata.com
Dr Sudeep Surender Gupta	Tata Memorial Centre	Dept. of Medical Oncology Homi Bhabha Block, Dr Ernest Borges Marg, Parel PIN 400012 Mumbai MAHARASHTRA	02224177201 02224165449 sudeepgupta@tatahospital.net
Dr Niti Raizada	Vikram Hospital Bengaluru Pvt. Ltd.	Senior Consultant, Medical Oncologist and Hemato-Oncologist, Dept. of Medical Oncology, #71/1, Millers Road, Opp. to St. Annes College PIN - 560052 Bangalore KARNATAKA	9901205647 nitiraizada@icloud.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Artemis Health Sciences Institutional Ethics Committee	Approved	17/06/2019	No
Cytecare Institutional Ethics Committee	Approved	07/09/2019	No
Institutional Ethics Committee Gleneagles Global Hospitals, Hyderabad	Approved	01/10/2019	No
Institutional Ethics Committee, Apollo Gleneagles Hospitals, Kolkata	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee, Deenanath Mangeshkar Hospital & Research Center	Approved	09/03/2020	No
Institutional Ethics Committee-Clinical Studies, Indraprastha Apollo Hospitals Delhi	Approved	12/03/2020	No
Institutional Review Board Rajiv Gandhi Cancer Institute and Research Centre	Approved	16/01/2020	No
Institutional Review Board Tata Medical Center, Kolkata	Approved	29/08/2019	No
Manavata Clinical Research Institute Ethics Committee	Approved	26/06/2019	No
Meditrina Institute	Approved	02/08/2019	No

Ethics Committee			
Meenakshi Mission Hospital and Research Centre (MMHRC) INSTITUTIONAL ETHICS COMMITTEE	Approved	24/02/2020	No
TATA Memorial Hospital Institutional Ethics Committee	Submittted/Under Review	No Date Specified	No
Vikram Hospital (Bangaluru) Pvt. Ltd. Ethics Committee	Approved	04/10/2019	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	02/08/2019

Health Condition / Problems Studied

Health Type	Condition
Patients	Malignant neoplasm of breast of unspecified site

Intervention / Comparator Agent

Type	Name	Details
Intervention	Capivasertib plus Paclitaxel	Capivasertib: Dose and frequency of dosing - will be given as an intermittent weekly dosing schedule. on weeks 1, 2, and 3 followed by 1 week off-treatment within each 28-day treatment cycle. Route of administration - Oral Duration of therapy - Study treatment will be continued until disease progression unless there is evidence of unacceptable toxicity, or if the patient requests to stop the study treatment. Paclitaxel: Dose and frequency of dosing- Patients will receive 3 consecutive weekly infusions followed by 1 week off-treatment within each 28-day treatment cycle. Route of administration - Intravenous infusion Duration of therapy - Paclitaxel treatment will be continued for at least 6 cycles unless the patient experiences unacceptable toxicity that is attributed directly to treatment with paclitaxel.
Comparator Agent	Placebo plus Paclitaxel	Placebo: Dose and frequency of dosing - will be given on an intermittent weekly dosing schedule on weeks 1, 2, and 3 followed by 1 week off-treatment within each 28-day treatment cycle. Route of administration - Oral Duration of therapy - Study treatment will be continued until disease progression unless there is evidence of unacceptable toxicity, or if the patient requests

		to stop the study treatment. Paclitaxel: Dose and frequency of dosing- Patients will receive 3 consecutive weekly infusions followed by 1 week off-treatment within each 28-day treatment cycle Route of administration - Intravenous infusion Duration of therapy - Paclitaxel treatment will be continued for at least 6 cycles unless the patient experiences unacceptable toxicity that is attributed directly to treatment with paclitaxel.

Inclusion Criteria

Inclusion Criteria

Age From	18.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	