An Indian multicentric open label prospective post marketing

First published: 10/09/2013

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Study Ongoing

Administrative details

EU PAS number

EUPAS3724

Study ID

40367

DARWIN EU® study

No

Study countries

☐ India

Study description

This is a single arm, open label, prospective, non-interventional, post marketing surveillance study in real-life clinical setting. This study has been planned to be conducted on 100 subjects at approximately 20 sites across India. The

recruitment period is 2 years. (ML28446)

Study status

Ongoing

Research institutions and networks

Institutions

F. Hoffmann-La Roche

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Institution

Multiple centres: 20 centres are involved in the study

Contact details

Study institution contact

Trial Information Support Line TISL
global.clinical_trial_registry@roche.com

Study contact

global.clinical_trial_registry@roche.com

Primary lead investigator

Jenny Petersen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/11/2012

Actual: 01/11/2012

Study start date

Planned: 28/11/2018

Actual: 05/12/2018

Date of final study report

Planned: 31/10/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Hoffmann-La Roche(Roche Products (India) Pvt, Ltd

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Non-EU RMP only

Other study registration identification numbers and links

ML28446

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

This multicenter prospective observational study will evaluate the safety and efficacy of Avastin (bevacizumab) in routine clinical practice in patients with advanced/metastatic epithelial ovarian cancer, fallopian tube cancer or primary

peritoneal cancer.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

AVASTIN

Study drug International non-proprietary name (INN) or common name

BEVACIZUMAB

Medical condition to be studied

Fallopian tube cancer

Ovarian epithelial cancer metastatic

Peritoneal carcinoma metastatic

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

100

Study design details

Outcomes

To determine the safety profile (all grade 3 and above adverse events) of bevacizumab when added to standard chemotherapy (carboplatin and paclitaxel) in front line advanced/metastatic epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer (FIGO Stage IIIb, IIIc and IV) in Indian population, Progression free survival (PFS)• Overall survival (OS)• Overall response rates (Complete response (CR)+ Partialresponse (PR)• Clinical benefit response rates (CR+PR+ Stable disease(SD)

Data analysis plan

All efforts will be made to regularly follow up patients to calculate Progression Free survival (PFS) and Overall Survival (OS).Kaplan-Meier procedure will be used to estimate the median PFS and OS for total as well as ECOG PS 0 and ECOG PS 1-2 at baseline. Log rank test will be used to compare the median survival time between subjects with ECOG PS 0 and ECOG PS 1-2 at baseline. The overall response rate (complete response CR + partial response PR) will be summarized using number and percentage along with two-sided 95% Pearson-Clopper confidence interval. Similarly, the Clinical Benefit Response rate (Complete Response + Partial Response + Stable Disease) will be summarized using number and percentage along with the twosided 95% Pearson-Clopper confidence interval.All statistical tests will be done at 5% level of significance.All patients with at least one follow up evaluation available wouldbe evaluated for efficacy.

Data management

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No