

Dose-finding of a fixed dose XM22 in patients with breast cancer receiving 4 cycles of chemotherapy versus 6 mg Neulasta®

Submission date 29/04/2008	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 22/05/2008	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 30/08/2011	Condition category Cancer	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
XM22-02-INT

Study information

Scientific Title

Study objectives

The primary objective of this study is dose-finding of a fixed dose of XM22.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee for Multi-Centric Clinical Trials of the University Hospital Motol, V uvalu 84, 150 06 Praha 5, Czech Republic. Date of approval: 09/04/2008 (ref: EK-279/08)

Primary study design

Interventional

Study design

Multinational, multicentre, randomised, double-blind, controlled study.

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Breast cancer

Interventions

Participants will be randomly allocated to the following two arms:

1. Neulasta®, 6 mg, administered subcutaneously once per chemotherapy cycle
2. XM22 administered subcutaneously once per chemotherapy cycle

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Neulasta®, XM22

Primary outcome(s)

Duration of severe neutropenia (DSN) in cycle 1

Key secondary outcome(s)

Incidence of febrile neutropenia (FN) in cycles 1, 2, 3 and 4

Completion date

28/02/2009

Eligibility

Key inclusion criteria

1. Men and women aged ≥ 18 years
2. Signed and dated written informed consent

3. Breast cancer high risk stage II, or stage III or IV
4. Patients planned/eligible to receive treatment with docetaxel/doxorubicin as routine chemotherapy for their breast cancer disease
5. Chemotherapy-naïve
6. Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2
7. ANC $\geq 1.5 \times 10^9/L$
8. Platelet count $\geq 100 \times 10^9/L$
9. Adequate cardiac function (including left ventricular ejection fraction $\geq 50\%$ as assessed by echocardiography or equivalent method within 4 weeks prior to randomisation)
10. Adequate hepatic function, i.e., alanine aminotransferase (ALT)/aspartate transaminase (AST) $< 2.5 \times$ upper limit of normal (ULN), alkaline phosphatase $< 5 \times$ ULN, bilirubin $< ULN$
11. Adequate renal function, i.e., creatinine $< 1.5 \times$ ULN

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Participation in a clinical trial within 30 days before randomisation
2. Previous exposure to filgrastim, pegfilgrastim, lenograstim, or other granulocyte-colony stimulating factors (G-CSFs) in clinical development
3. Known hypersensitivity to docetaxel
4. Underlying neuropathy of grade 2 or higher
5. Treatment with systemically active antibiotics within 72 hours before chemotherapy
6. Treatment with lithium
7. Chronic use of oral corticosteroids
8. Prior radiation therapy within 4 weeks before randomisation
9. Prior bone marrow or stem cell transplantation
10. Prior malignancy within the previous 5 years other than basal cell or squamous cell carcinomas or in situ carcinoma of the cervix
11. Any illness or condition that in the opinion of the investigator may affect the safety of the patient or the evaluation of any study endpoint
12. Pregnant or nursing women. Women of child bearing potential who do not agree to use a highly effective method of birth control during the entire duration of the study. Highly effective methods of birth control are defined as those which result in a low failure rate (i.e. less than 1% per year) when used consistently and correctly such as implants, injectables, combined oral contraceptives, hormonal IUDs, sexual abstinence or vasectomised partner. Female patients will be considered to be of childbearing potential unless surgically sterilised by hysterectomy or bilateral tubal ligation, or post-menopausal for at least two years.

Date of first enrolment

30/04/2008

Date of final enrolment

28/02/2009

Locations

Countries of recruitment

Czech Republic

Germany

Hungary

Poland

Romania

Russian Federation

Ukraine

Study participating centre

Universitäts-Frauenklinik

Frankfurt

Germany

60596

Sponsor information

Organisation

BioGeneriX AG (Germany)

ROR

<https://ror.org/03xa4xh46>

Funder(s)

Funder type

Industry

Funder Name

BioGeneriX AG (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration