

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

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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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)

## **Study design**

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

## **Primary study design**

Interventional

## **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  $\geq 18$  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  $\leq 2$
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