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Efficacy and safety of XM22 in patients with non small cell lung cancer receiving cisplatin / etoposide chemotherapy

Submission date 22/04/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/06/2010	**Overall study status** Completed	
Last Edited 16/01/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Peter Bias

Contact details
Merckle GmbH
A Member of the ratiopharm Group
Clinical Research
Graf-Arco-Straße 3
Ulm
Germany
89075

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
XM22-04

Study information

Scientific Title
Efficacy and safety of XM22 in patients with non small cell lung cancer receiving cisplatin / etoposide chemotherapy. A multinational, multicentre, randomised, double-blind placebo-controlled study

Study objectives
Demonstration of superiority of XM22 versus placebo when administered for up to a maximum of four cycles chemotherapy (CTX) in patients with non small cell lung cancer (NSCLC)

Ethics approval required
Old ethics approval format

Ethics approval(s)
At each study centre, the protocol (dated 01/10/2009) and informed consent form for this study were reviewed and approved by Independent Ethic Committees before inclusion of patients. Amendments to the protocol will be reviewed and approved in the same manner before being implemented

Study design
Multinational multicentre randomised double blind placebo controlled phase III study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
NSCLC patients with chemotherapy induced neutropenia

Interventions
XM22: 1 syringe 6 mg per cycle (cycles 1-4)
Placebo: 1 syringe per cycle (cycles 1-4)
The duration of the study will be 12 weeks. The duration of follow up will be 360 days.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
XM22

Primary outcome measure
Incidence of febrile neutropenia (FN) in the first cycle of chemotherapy

Secondary outcome measures
1. Incidence of febrile neutropenia in cycles 2, 3 and 4 and across all cycles
2. Duration and incidence of severe neutropenia, defined as grade 4 neutropenia with an ANC <0.5 x 10*9/L in cycles 1, 2, 3 and 4
3. Duration and incidence of very severe neutropenia, defined as ANC <0.1 x 10*9/L in cycles 1, 2, 3 and 4
4. Depth of ANC nadir in all cycles
5. Time to ANC nadir in cycles 1, 2, 3 and 4
6. Time to ANC recovery in all cycles
7. Percentage of actually delivered vs. scheduled cumulative chemotherapy dose
8. Proportion of patients with chemotherapy doses reduced, omitted, or delayed
9. Number of days of delay of chemotherapy
10. Overall quality of life as measured by the EORTC QLQ-C30 (version 3) and the EORTC QLQ-LC13
11. Time in hospital and time in intensive care unit due to febrile neutropenia or connected infections
12. Incidence of treatment with i.v. antibiotics due to FN or connected infections
13. Incidence of patients requiring prophylactic open treatment

Overall study start date
01/05/2010

Completion date
01/03/2012

Eligibility

Key inclusion criteria
1. Provide signed and dated written informed consent
2. Men and women aged ≥18
3. The patient must be able to understand and follow instructions and must be able to participate in the study for the entire period
4. Patients with NSCLC stage IIIB/IV, histologically or cytologically documented
5. Patients planned and eligible to receive 4 cycles of the predefined cisplatin / etoposide-based, myelosuppressive CTX
6. Life-expectancy of at least 4 months
7. CTX naïve
8. Eastern Cooperative Oncology Group (ECOG) performance status ≤2
9. Absolute Neutrophil Count (ANC) ≥1.5 x 10*9/L
10. Platelet count ≥100 x 10*9/L
11. Adequate hepatic function, i.e. ALT and AST <2.5 x ULN, alkaline phosphatase <5 x ULN,

bilirubin <ULN
12. Adequate renal function, i.e. creatinine <1.5 x ULN
13. Adequate hepatic, cardiac, bone marrow and renal function for the chosen CTX regimen

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
375 (250 XM22 group, 125 placebo group)

Key exclusion criteria
1. Participation in a clinical trial within 30 days before randomisation.
2. Previous exposure to filgrastim, pegfilgrastim or lenograstim or other G-CSFs in clinical development less than 6 months before randomisation.
3. Known hypersensitivity to filgrastim, pegfilgrastim, lenograstim, cisplatin or etoposide.
4. Patient planned for non-myelosuppressive CTX.
5. Patients with an individual high risk for febrile neutropenia in respect of the cisplatin /etoposide CTX according to the assessment of the investigator. Risk factors are age >65 years, low performance status, poor nutritional status, and liver, renal or cardiovascular disease.
6. Patient meeting any contraindication for the chosen CTX regimen.
7. Treatment with systemically active antibiotics within 72 hours before CTX.
8. Treatment with lithium at inclusion or planned during the entire study.
9. Patient to be treated with combined chemo-/ radiotherapy during the foreseen participation in this study.
10. Chronic use of oral corticosteroids (except low dose chronic treatment with ≤20 mg/day prednisolone or equivalent dose for chronic obstructive pulmonary disease).
11. Prior radiation therapy or tumour surgery within 4 weeks before randomisation.
12. Prior bone marrow or stem cell transplantation.
13. Prior malignancy within the preceding 5 years other than non-melanoma skin cancer or in situ cervical carcinoma.
14. 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.
15. 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 child-bearing potential unless surgically sterilised by hysterectomy or bilateral tubal ligation, or post-menopausal for at least two years (Postmenopausal is defined as the time after which a woman has experienced twelve consecutive months of amenorrhea without a period).

Date of first enrolment
01/05/2010

Date of final enrolment
01/03/2012

Locations

Countries of recruitment
Belarus

Bosnia and Herzegovina

Bulgaria

Germany

Poland

Romania

Russian Federation

Serbia

Ukraine

Study participating centre
Merckle GmbH
Ulm
Germany
89075

Sponsor information

Organisation
BioGeneriX AG (Germany)

Sponsor details
High-Tech-Park Neckarau
Janderstraße 3
Mannheim
Germany
68199

Sponsor type

Industry

Website
http://www.biogenerix.com

ROR
https://ror.org/03xa4xh46

Funder(s)

Funder type
Industry

Funder Name
BioGeneriX AG (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/07/2015	16/01/2019	Yes	No
Results article	results	01/12/2016	16/01/2019	Yes	No