ISRCTN09512688 https://doi.org/10.1186/ISRCTN09512688

A First-in-Human study in healthy male volunteers to investigate the safety, tolerability and pharmacokinetics of recombinant human soluble Fc gamma receptor IIb, sFcγRIIb (SM101) administered intravenously as single ascending doses

Submission date
20/08/2009

Registration date
28/09/2009

Last Edited
28/09/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Andreas Schroedter

Contact details
FOCUS Clinical Drug Development GmbH
Stresemannallee 6
Neuss
Germany
41460

Additional identifiers

Protocol serial number
SM101-101-hv-08

Study information

Scientific Title
A First-in-Human Phase I, double-blind, randomised, placebo-controlled study in healthy male volunteers to investigate the safety, tolerability and pharmacokinetics of recombinant human soluble Fc gamma receptor IIb, sFcγRIIb (SM101) administered intravenously as single ascending doses

Study objectives
The primary objective of this first-in-human study is to evaluate the safety and tolerability of escalating single doses of intravenously administered sFcγRIIb (SM101).

The secondary objective of this study is to assess the pharmacokinetic profile of sFcγIIRb (SM101) in healthy male subjects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee approval was obtained from the Aerztekammer Nordrhein on 08/04/2009 (ref 2008402)

Study design
Single-centre double-blind randomised placebo controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic Adult Idiopathic Thrombocytopenic Purpura

Interventions
sFcγRIIb (SM101) is a recombinant, soluble, non-glycosylated version of the human Fcγ receptor FcγRIIb.

Seven consecutive regular dose groups (0.004, 0.04, 0.4, 1, 2.5, 5 and 10 mg/ kg) will receive one single intravenous administration of sFcγRIIb (SM101) or placebo over 60 minutes under fasted conditions. Further 4 intermediate dose groups may be included, if deemed necessary for safety reasons. Each dose group consists of 6 subjects (4 verum, 2 placebo). Decision on dose escalation will be subject to an independent DSMB.

After a 14-day screening period the subjects will either be enrolled in the verum or placebo arm and will be hospitalised one day before treatment start (day -1). They will be discharged 72 hours after dosing (day 4) and return to the site on day 6, 8 and 12 for ambulatory visits. The active part of the study will be completed on day 15 (conclusion visit). Subjects will attend a follow-up visit 6 months and 1 year after dosing to collect further safety data.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Recombinant human soluble Fc gamma receptor IIb, sFcγRIIb (SM101)

Primary outcome(s)
Safety assessments:
1. Haematology, clinical chemistry, coagulation parameters, urinalysis (screening, day -1, pre-dose and 6, 24, 48 and 72 hours after drug administration and on days 6, 8, 12, and 15, follow-up (FU) at 6 months and FU 1 year)
2. IL-6 and CRP (pre-dose, 0.5, 1, 2, 4, 6, 8, 12, 24, 36, 48, 72 hours after start of infusion and on days 6, 8, 12 and day 15, FU 6 months and FU 1 year)
3. Vital signs, 12-lead ECG (screening, day -1, and 8, 10, 12, 16, 24, 36, 48 and 72 hours after drug administration and on day 15, FU 6 months and FU 1 year)
4. Physical examination (screening, day -1, 24 and 48 hours after drug administration and on day 4 before discharge, day 15, FU 6 months and FU 1 year)
5. Local tolerability (day 1 at 0.25, 0.5, 1, 2, 4 and 12 hours after start of infusion, days 2 and 3 and before discharge on day 4)
6. Adverse events (The National Cancer Institute [NCI] Common Terminology Criteria for Adverse Events [CTCAE] v 3.0)

Key secondary outcome(s))
Pharmacokinetic analysis:
Pre-dose, 0.25, 0.5, 1, 1.25, 1.5, 2, 4, 6, 8, 10, 12, 16, 24, 36, 48 and 72 hours after start of infusion

Completion date
02/10/2009

Eligibility

Key inclusion criteria
1. Male, Caucasian subjects aged between 18-40 years (inclusive)
2. Healthy subjects as determined by medical history, physical examination including vital signs, electrocardiography (ECG) and clinical laboratory testing
3. Body weight between 70-90 kg and body mass index (BMI) between 19 and 28 kg/m^2, extremes included
4. ECG recording based on a 12-lead ECG which is normal (PR <210 ms, QRS <110 ms, QTC 380-430 ms) or contains only slight deviations deemed to be of no clinical relevance by the investigator
5. Normal vital signs (after 5 minutes resting), blood pressure values (systolic >=100 and <=140 mmHg, diastolic >=50 and <=90 mmHg), heart rate between 40 and 90 beats per minute (bpm), body temperature <37.5°C
6. Subjects who are able and willing to give written informed consent
7. Normal white blood cell count, C-reactive protein (CRP) and interleukin-6 (IL-6) at screening

and on the day before treatment start
8. Subjects must be using two acceptable methods for contraception (e.g. spermicide and condom) during the study and refrain from fathering a child in the 3 months following dosing

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
40 years

Sex
Male

Key exclusion criteria
1. In the opinion of the investigator subjects with clinically significant history or presence of cardiovascular, respiratory, renal, hepatic, metabolic, endocrinological, gastrointestinal, hematological, neurological, dermatological, psychiatric diseases, cancer or other major diseases
2. Infection or known inflammatory process
3. Subjects with known autoimmune diseases or immunodeficiency or known family history of autoimmune diseases or immunodeficiency
4. Clinical significant allergic disease
5. Subjects with known serum hepatitis or who are carriers of the hepatitis B surface antigen or hepatitis C antibodies or with a positive result to the test for HIV 1/2 antibodies
6. Subjects who have received an investigational drug and/or a vaccination within 3 months prior to start of the treatment in study and those who anticipate receipt of a vaccine within 2 months after the last dose of study drug
7. Subjects, who have received prior treatment within 1 year with monoclonal antibodies or other biologic agents
8. The use of any concomitant prescription or non-prescription medication within 14 days prior to the first administration of study medication until follow-up; or treatment with medication that may affect immune function (e.g. immunoglobulins, corticosteroids) within 6 months before dosing
9. Donation of blood (>400 ml) or blood products within the last 3 months prior to admission to the clinical unit or plasmapheresis within 4 weeks prior to study start
10. Definite or suspected personal history of adverse reactions or hypersensitivity to drugs especially to the trial compounds (E. coli-derived proteins, Tween, mannitol) or to compounds with a similar structure
11. Subjects who drink more than 5 cups or glasses of coffee, tea and/or cola per day
12. Subjects with a presence or history of drug and/or alcohol abuse or an average daily intake of more than 20 g alcohol per day
13. Subjects with a positive test for alcohol or drugs at screening and on the day before treatment start

14. Smokers of >5 cigarettes/day or equivalent
15. Subjects who are unlikely to be compliant and attend scheduled clinic visits as required
16. Participation in this study on a previous dose level

Date of first enrolment
30/04/2009

Date of final enrolment
02/10/2009

Locations

Countries of recruitment
Germany

Study participating centre
FOCUS Clinical Drug Development GmbH
Neuss
Germany
41460

Sponsor information

Organisation
SuppreMol GmbH (Germany)

ROR
https://ror.org/05jgtkc28

Funder(s)

Funder type
Government

Funder Name
German Federal Ministry of Education and Research (Bundesministerium Fur Bildung und Forschung [BMBF]) (Germany) , Grant number: 01GU0623

Results and Publications

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes