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An open-label extension study following the HRM4396B/3001 study (a double-blind, placebo-controlled, parallel arms, dose response study of two doses of HMR4396 versus placebo for anaemia in subjects treated with chemotherapy)

Submission date
12/06/2007

Registration date
19/07/2007

Last Edited
15/08/2008

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 Chris Freitag

Contact details
Shire contact for trial - no PI identified
Hampshire International Business Park
Lime Tree Way
Basingstoke
United Kingdom
RG24 8EP

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HMR4396B/3002

Study information

Scientific Title

Study objectives
Advanced cancer is frequently associated with significant anaemia. The causes of this anaemia are multi-factorial and may include the cytotoxic effects of chemotherapeutic agents on bone marrow.

Primary objective was to offer a 12-week open-label extension of treatment to subjects having completed the HMR4396B/3001 study in order to collect longer term safety and efficacy data in this population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This was a multi-national, multi-centre trial with 39 centres in the United States. The independent ethics committee from each of the sites approved the study before the first subject was enrolled.

Study design
Phase III, open-label extension study following the HMR4396B/3001 study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Anaemia

Interventions
The intervention was administration of HMR4396 at a starting dose of 150 U/kg three times weekly for 12 weeks. The dose could be increased to 300 U/kg after four weeks if the subjects haemoglobin was less than or equal to 12 g/dL.

Quality of life was evaluated using the Functional Assessment of Cancer Therapy - Anaemia (FACT-An) questionnaire.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
HMR4396

Primary outcome measure
The primary efficacy endpoints in this study were:
1. Change in haemoglobin from baseline, and
2. The percentage of subjects receiving red blood cell transfusions during the study

Secondary outcome measures
The secondary efficacy endpoints were:
1. Number of red blood cell transfusions received during weeks 1 - 12
2. Number of units transfused during weeks 1 - 12
3. Change from baseline in haematocrit

Overall study start date
03/08/2000

Completion date
16/09/2002

Eligibility

Key inclusion criteria
1. Completion of the HMR4396B/3001 study
2. Informed consent was obtained from all subjects before enrolment into the study

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
149 subjects enrolled into the study, of which 100 completed treatment with HMR4396. Nine subjects were enrolled but not treated with study medication, and 49 were withdrawn prior to study completion.

Key exclusion criteria

Subjects meeting any of the following criteria were not to be included in the study:
1. Pregnant
2. Breast feeding
3. Likelihood of requiring treatment during the study period with drugs not permitted by the study protocol
4. Current drug abuse
5. Mental condition rendering the subject unable to understand the nature, scope and possible consequences of the study

Date of first enrolment
03/08/2000

Date of final enrolment
16/09/2002

Locations

Countries of recruitment
England

United Kingdom

United States of America

Study participating centre
Shire contact for trial - no PI identified
Basingstoke
United Kingdom
RG24 8EP

Sponsor information

Organisation
Hoechst Marion Roussel (Shire Pharmaceuticals) (France)

Sponsor details
102 Route de Noisy
Romainville, Cedex
France
93235

Sponsor type
Industry

Website

http://www.shire.com/shire/

ROR
https://ror.org/02n6c9837

Funder(s)

Funder type
Industry

Funder Name
Hoechst Marion Roussel (Shire Pharmaceuticals) (France)

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