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

Submission date 12/06/2007	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 19/07/2007	Overall study status Completed	 Statistical analysis plan Results
Last Edited 15/08/2008	Condition category Haematological Disorders	 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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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

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