

# 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)

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

Dr Chris Freitag

### Contact details

Shire contact for trial - no PI identified  
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RG24 8EP

## Additional identifiers

### Protocol serial number

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.

### **Primary study design**

Interventional

### **Study design**

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

### **Study type(s)**

Treatment

### **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(s)**

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

### **Key secondary outcome(s)**

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

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **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**

United Kingdom

England

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)

**ROR**

<https://ror.org/02n6c9837>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Hoechst Marion Roussel (Shire Pharmaceuticals) (France)

## Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration