ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 06/06/2014

A Study of Avastin (Bevacizumab) in Patients With Multiple Myeloma

This study has been terminated.
(The study was discontinued prematurely by the sponsor due to a lack of recruitment.)

Sponsor:	Hoffmann-La Roche
Collaborators:	
Information provided by (Responsible Party):	Hoffmann-La Roche
ClinicalTrials.gov Identifier:	NCT02079519

Purpose

This study evaluated the efficacy and safety of Avastin (bevacizumab, 5 mg/kg intravenously every 2 weeks) in patients with multiple myeloma, relapsed/refractory after at least 2 lines of prior therapy.

Condition	Intervention	Phase
Multiple Myeloma	Drug: Bevacizumab	Phase 2

Study Type: Interventional
Study Design: Treatment, Single Group Assignment, Open Label, N/A, Safety/Efficacy Study
Official Title: Bevacizumab as Treatment for Patients With Relapsed/Refractory Multiple Myeloma

Further study details as provided by Hoffmann-La Roche:

Primary Outcome Measure:

- Percentage of Participants With a Complete Response or a Partial Response [Time Frame: Baseline to the end of the study (up to 1 year)] [Designated as safety issue: No]

  A complete response was defined as the disappearance of the original monoclonal protein from the blood and urine on at least 2 determinations 6 weeks apart; < 5% plasma cells in the bone marrow on at least 2 determinations 6 weeks apart; if a skeletal survey is available, no increase in the size or number of lytic bone lesions; and the disappearance of soft tissue plasmacytomas for at least 6 weeks. A partial response was defined as a ≥ 50%

reduction of monoclonal protein in the blood on at least 2 determinations 6 weeks apart; if present, reduction in 24-hour urinary light chain excretion by either ≥ 90% or to < 200 mg for at least 2 determinations 6 weeks apart; ≥ 50% reduction in the size of tissue plasmacytomas for at least 6 weeks; and if a skeletal survey is available, no increase in the size or number of lytic bone lesions.

Secondary Outcome Measures:

- Progression-free Survival [Time Frame: Baseline to the end of the study (up to 1 year)] [Designated as safety issue: No]
  Progression-free survival was defined as the time from the first dose of study drug to disease progression or death due to progression.
- Overall Survival [Time Frame: Baseline to the end of the study (up to 1 year)] [Designated as safety issue: No]
  Overall survival was defined as the time from the first dose of study medication until death.

Enrollment: 10
Study Start Date: May 2006
Primary Completion Date: May 2008
Study Completion Date: May 2008

Arms	Assigned Interventions
Experimental: Bevacizumab 5 mg/kg Participants received bevacizumab 5 mg/kg intravenously every 2 weeks for 6 months until disease progression or termination of the study. Participants showing a continuous benefit of therapy could receive treatment for a maximum of 12 months.	Drug: Bevacizumab Bevacizumab was provided as a concentrate in vials. Other Names: Avastin RO 487-6646

Eligibility

Ages Eligible for Study: 19 Years to 75 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Adult patients, 19-75 years of age
- Multiple myeloma.
- Progressive disease after at least 2 lines of prior therapy.

Exclusion Criteria:

- Non-secretory myeloma.
- History of malignancy, other than squamous cell cancer, basal cell cancer, or cancer in situ of the cervix within the last 5 years.
- Major surgical procedure, open biopsy, or significant traumatic injury within 28 days prior to study treatment start.
- Clinically significant cardiac disease.

Contacts and Locations

Locations

Austria

Salzburg, Austria, 5020
Wien, Austria, 1140
Wien, Austria, 1090
Wien, Austria, 1160

Investigators

Study Chair:	Clinical Trials	Hoffmann-La Roche

More Information

Responsible Party:	Hoffmann-La Roche
Study ID Numbers:	ML18704
Health Authority:	Austria: Bundesamt für Sicherheit im Gesundheitswesen

Study Results

Participant Flow

Reporting Groups

	Description
Bevacizumab 5 mg/kg	Participants received bevacizumab 5 mg/kg intravenously every 2 weeks for 6 months until disease progression or termination of the study. Participants showing a continuous benefit of therapy could receive treatment for a maximum of 12 months.

Overall Study

	Bevacizumab 5 mg/kg
Started	10
Completed	0
Not Completed	10
Disease Progression	9
Adverse Event	1

Baseline Characteristics

Analysis Population Description

Intent-to-treat population: All participants who received at least 1 dose of study drug.

Reporting Groups

	Description
Bevacizumab 5 mg/kg	Participants received bevacizumab 5 mg/kg intravenously every 2 weeks for 6 months until disease progression or termination of the study. Participants showing a continuous benefit of therapy could receive treatment for a maximum of 12 months.

Baseline Measures

	Bevacizumab 5 mg/kg
Number of Participants	10
Age, Continuous [units: years] Mean (Standard Deviation)	68.6 (9.9)
Gender, Male/Female [units: participants]	
Female	7
Male	3

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants With a Complete Response or a Partial Response
Measure Description	A complete response was defined as the disappearance of the original monoclonal protein from the blood and urine on at least 2 determinations 6 weeks apart; < 5% plasma cells in the bone marrow on at least 2 determinations 6 weeks apart; if a skeletal survey is available, no increase in the size or number of lytic bone lesions; and the disappearance of soft tissue plasmacytomas for at least 6 weeks. A partial response was defined as a ≥ 50% reduction of monoclonal protein in the blood on at least 2 determinations 6 weeks apart; if present, reduction in 24-hour urinary light chain excretion by either ≥ 90% or to < 200 mg for at least 2 determinations 6 weeks apart; ≥ 50% reduction in the size of tissue plasmacytomas for at least 6 weeks; and if a skeletal survey is available, no increase in the size or number of lytic bone lesions.
Time Frame	Baseline to the end of the study (up to 1 year)
Safety Issue?	No

Analysis Population Description

Intent-to-treat population: All participants who received at least 1 dose of study drug.

Reporting Groups

	Description
Bevacizumab 5 mg/kg	Participants received bevacizumab 5 mg/kg intravenously every 2 weeks for 6 months until disease progression or termination of the study. Participants showing a continuous benefit of therapy could receive treatment for a maximum of 12 months.

Measured Values

	Bevacizumab 5 mg/kg
Number of Participants Analyzed	10
Percentage of Participants With a Complete Response or a Partial Response [units: Percentage of participants]	0.0

2. Secondary Outcome Measure:

Measure Title	Progression-free Survival
Measure Description	Progression-free survival was defined as the time from the first dose of study drug to disease progression or death due to progression.
Time Frame	Baseline to the end of the study (up to 1 year)
Safety Issue?	No

Outcome Measure Data Not Reported

3. Secondary Outcome Measure:

Measure Title	Overall Survival
Measure Description	Overall survival was defined as the time from the first dose of study medication until death.
Time Frame	Baseline to the end of the study (up to 1 year)
Safety Issue?	No

Outcome Measure Data Not Reported

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	Intent-to-treat population: All participants who received at least 1 dose of study drug.

Reporting Groups

	Description
Bevacizumab 5 mg/kg	Participants received bevacizumab 5 mg/kg intravenously every 2 weeks for 6 months until disease progression or termination of the study. Participants showing a continuous benefit of therapy could receive treatment for a maximum of 12 months.

Serious Adverse Events

	Bevacizumab 5 mg/kg
	Affected/At Risk (%)
Total	5/10 (50%)
Blood and lymphatic system disorders	
Febrile neutropenia [A] †	1/10 (10%)
Thrombocytopenia [A] †	1/10 (10%)
General disorders	
General physical health deterioration [A] †	2/10 (20%)
Pyrexia [A] †	1/10 (10%)
Injury, poisoning and procedural complications	
Humerus fracture [A] †	1/10 (10%)
Metabolism and nutrition disorders	
Hypercalcaemia [A] †	1/10 (10%)
Hyperglycaemia [A] †	1/10 (10%)
Nervous system disorders	
Headache [A] †	1/10 (10%)
Vascular disorders	

	Bevacizumab 5 mg/kg
	Affected/At Risk (%)
Haemorrhage [A] †	1/10 (10%)
Hypertension [A] †	1/10 (10%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (11.0)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	Bevacizumab 5 mg/kg
	Affected/At Risk (%)
Total	0/10 (0%)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The Study being conducted under this Agreement is part of the Overall Study. Investigator is free to publish in reputable journals or to present at professional conferences the results of the Study, but only after the first publication or presentation that involves the Overall Study. The Sponsor may request that Confidential Information be deleted and/or the publication be postponed in order to protect the Sponsor's intellectual property rights.

Results Point of Contact:

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