ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 05/27/2014

ClinicalTrials.gov ID: NCT00754650

Study Identification

Unique Protocol ID:	ML21206
Brief Title:	A Proof of Concept Study of the Safety, Tolerability, and Efficacy of Avastin (Bevacizumab) in Patients With Chemo-naive Chronic Lymphocytic Leukemia
Official Title:	ML21206 - Bevacizumab in Chronic Lymphocytic Leukemia: A Proof of Concept Study
Secondary IDs:	2007-004824-19 [EudraCT Number]

Study Status

Record Verification:	May 2014
Overall Status:	Completed
Study Start:	September 2008
Primary Completion:	March 2009 [Actual]
Study Completion:	March 2009 [Actual]

Sponsor/Collaborators

Sponsor:	Hoffmann-La Roche
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	No
IND/IDE Protocol?:	No

Review Board:	Approval Status: Approved Approval Number: 944 Board Name: Ethikkommission fur das Bundesland Salzburg Board Affiliation: unknown Phone: +43-0662-8042-2375 Email: ethikkommission@salzburg.gv.at
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	Austria: Federal Agency for Safety in Health Care

Study Description

Brief Summary:	This single arm study evaluated the bone marrow response, safety, and tolerability of 6 months treatment with Avastin (bevacizumab) monotherapy in patients with chronic lymphocytic leukemia. Patients received 8 cycles (21 days duration) of Avastin monotherapy (15mg/kg) with 6 months of follow-up.
Detailed Description:	

Conditions

Conditions:	Lymphocytic Leukemia, Chronic
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Single Group Assignment
Number of Arms:	1
Masking:	Open Label
Allocation:	N/A
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	2 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Bevacizumab 15 mg/kg Participants received bevacizumab 15 mg/kg intravenously on Day 1 of each 3-week cycle for 8 cycles.	Drug: Bevacizumab Bevacizumab was supplied as a sterile liquid in single-use vials. Other Names: • Avastin

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Male or female patients, ≥ 18 years of age.
- B-chronic lymphocytic leukemia not yet requiring treatment.
- Eastern Cooperative Oncology Group (ECOG) performance status 0-2.
- No previous treatment of chronic lymphocytic leukemia (CLL) by chemotherapy, radiotherapy, or immunotherapy.
- Life expectancy > 6 months.

Exclusion Criteria:

- Central nervous system (CNS) involvement by lymphoma or any evidence of spinal cord compression.
- Computed tomography (CT) scan based evidence of tumor invading major blood vessels.
- Gastrointestinal (GI) tract involvement by CLL.
- Active viral, bacterial, or fungal infection.
- Uncontrolled hypertension, cerebrovascular accident/stroke (≤ 6 months prior to randomization), myocardial infarction (≤ 6 months prior to randomization), unstable angina (≥ New York Heart Association (NYHA) Grade IV), thrombosis within 6 months before enrollment, NYHA Grade II congestive heart failure, or serious cardiac arrhythmia requiring ongoing medication.

Contacts/Locations

Study Officials: Clinical Trials

Study Director
Hoffmann-La Roche

Locations: Austria
Salzburg, Austria, 5020

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
Bevacizumab 15 mg/kg	Participants received bevacizumab 15 mg/kg intravenously on Day 1 of each 3-week cycle for 8 cycles.

Overall Study

	Bevacizumab 15 mg/kg
Started	2
Completed	0
Not Completed	2
Disease Progression	2

Baseline Characteristics

Analysis Population Description
Intent-to-treat population: All participants who received at least 1 administration of the study drug.

Reporting Groups

	Description
Bevacizumab 15 mg/kg	Participants received bevacizumab 15 mg/kg intravenously on Day 1 of each 3-week cycle for 8 cycles.

Baseline Measures

	Bevacizumab 15 mg/kg
Number of Participants	2
Age, Continuous [units: years] Mean (Standard Deviation)	60.0 (9.9)
Gender, Male/Female [units: participants]	
Female	1
Male	1

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Bone Marrow Response
Measure Description	Bone marrow response was defined as the change in percentage of infiltration at the interim staging (after 4 cycles of treatment) and the end of treatment.
Time Frame	Baseline to the end of treatment (up to 24 weeks)
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Bevacizumab 15 mg/kg	Participants received bevacizumab 15 mg/kg intravenously on Day 1 of each 3-week cycle for 8 cycles.

Measured Values

	Bevacizumab 15 mg/kg
Number of Participants Analyzed	2
Bone Marrow Response [units: Percentage of infiltration]	

	Bevacizumab 15 mg/kg
Median (Inter-Quartile Range)	
Interim staging	-20.0 (-40.0 to 0.0)
End of treatment	-20.0 (-40.0 to 0.0)

2. Secondary Outcome Measure:

Measure Title	Best Overall Response (BOR)
Measure Description	The percentage of participants in each BOR category (complete response (CR), partial response (PR), stable disease (SD), or progressive disease (PD)) is reported. CR was defined as the disappearance of all target (TL) and non-target lesions (non-TL). PR was defined as ≥ 30% decrease in the sum of the longest diameter (SLD) of TLs, taking as reference the baseline SLD, or the persistence of 1 or more non-TLs. For TLs, SD was defined as neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD, taking as reference the smallest SLD since treatment started. For non-TLs, SD was defined as the persistence of 1 or more lesions. PD was defined as ≥ 20% increase in the sum of the longest diameter of TLs, taking as reference the smallest SLD recorded since treatment started, the unequivocal progression of existing non-TLs, or the appearance of 1 or more new lesions.
Time Frame	Baseline to the end of treatment (up to 24 weeks)
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Bevacizumab 15 mg/kg	Participants received bevacizumab 15 mg/kg intravenously on Day 1 of each 3-week cycle for 8 cycles.

Measured Values

	Bevacizumab 15 mg/kg
Number of Participants Analyzed	2
Best Overall Response (BOR) [units: Percentage of participants]	
Interim staging - Complete response	0.0
Interim staging - Partial response	0.0
Interim staging - Stable disease	50.0

	Bevacizumab 15 mg/kg
Interim staging - Progressive disease	50.0
End of treatment - Complete response	0.0
End of treatment - Partial response	0.0
End of treatment - Stable disease	0.0
End of treatment - Progressive disease	100.0

Reported Adverse Events

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

Reporting Groups

	Description
Bevacizumab 15 mg/kg	Participants received bevacizumab 15 mg/kg intravenously on Day 1 of each 3-week cycle for 8 cycles.

Serious Adverse Events

	Bevacizumab 15 mg/kg
	Affected/At Risk (%)
Total	0/2 (0%)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Bevacizumab 15 mg/kg
	Affected/At Risk (%)
Total	2/2 (100%)
Blood and lymphatic system disorders	
Thrombocytopenia [A] †	1/2 (50%)
General disorders	

	Bevacizumab 15 mg/kg
	Affected/At Risk (%)
Fatigue [A] †	1/2 (50%)
Infections and infestations	
Nasopharyngitis [A] †	2/2 (100%)
Vascular disorders	
Hypertension [A] †	1/2 (50%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (13.1)

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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