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Trial record **1 of 1** for: CAMN107A2302

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Nilotinib vs Imatinib in Adult Patients With Philadelphia (Ph+) Chronic Myelogenous Leukemia in Chronic Phase (CML-CP) (ENEST)

This study has been terminated.

(This study was terminated due to limited enrollment.)

Sponsor:
Novartis Pharmaceuticals

Information provided by (Responsible Party):
Novartis (Novartis Pharmaceuticals)

ClinicalTrials.gov Identifier:
NCT00519090

First received: August 17, 2007
Last updated: November 4, 2011
Last verified: November 2011
History of Changes

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Results First Received: November 11, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Myelogenous Leukemia
Interventions:	Drug: Imatinib Drug: Nilotinib (AMN107)

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Nilotinib (AMN107)	Patients received 400 mg twice daily, 2 x 200 mg capsules twice daily.
Imatinib	Patients received 400 mg twice daily. Capsules were available in 100 mg and 400 mg formulations.

Participant Flow: Overall Study

	Nilotinib (AMN107)	Imatinib
STARTED	**2**	**4**
COMPLETED	**2**	**4**
NOT COMPLETED	**0**	**0**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

No text entered.

Reporting Groups

	Description
Nilotinib (AMN107)	Patients received 400 mg twice daily, 2 x 200 mg capsules twice daily.
Imatinib	Patients received 400 mg twice daily. Capsules were available in 100 mg and 400 mg formulations.
Total	Total of all reporting groups

Baseline Measures

	Nilotinib (AMN107)	Imatinib	Total
Number of Participants [units: participants]	**2**	**4**	**6**
Age [units: participants]			
<=18 years	**0**	**0**	**0**
Between 18 and 65 years	**0**	**4**	**4**
>=65 years	**2**	**0**	**2**
Age [units: years] Mean (Standard Deviation)	**69.5 (4.949747)**	**45.5 (12.06924)**	**54 (15.6812)**
Gender [units: participants]			
Female	**1**	**3**	**4**
Male	**1**	**1**	**2**
Region of Enrollment [units: participants]			
Belgium	**1**	**0**	**1**
Germany	**0**	**1**	**1**

Japan	**1**	**0**	**1**
Korea, Republic of	**0**	**1**	**1**
Poland	**0**	**2**	**2**

Outcome Measures

Hide All Outcome Measures

1. Primary: Complete Cytogenetic Response Rate(CCyR) in Patients Who Had a Suboptimal Cytogenetic Response on Imatinib [Time Frame: 12 months]

Measure Type	Primary
Measure Title	Complete Cytogenetic Response Rate(CCyR) in Patients Who Had a Suboptimal Cytogenetic Response on Imatinib
Measure Description	Due to early termination of the trial, the number of patients was too small and imbalanced and therefore analysis was not performed.
Time Frame	12 months
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Nilotinib (AMN107)	Patients received 400 mg twice daily, 2 x 200 mg capsules twice daily.
Imatinib	Patients received 400 mg twice daily. Capsules were available in 100 mg and 400 mg formulations.

Measured Values

	Nilotinib (AMN107)	Imatinib
Number of Participants Analyzed **[units: participants]**	**0**	**0**
Complete Cytogenetic Response Rate(CCyR) in Patients Who Had a Suboptimal Cytogenetic Response on Imatinib **[units: percent of participants]**		

No statistical analysis provided for Complete Cytogenetic Response Rate(CCyR) in Patients Who Had a Suboptimal Cytogenetic Response on Imatinib

2. Secondary: Durable Complete Cytogenetic Response Rate [Time Frame: 24 months]

Measure Type	Secondary
Measure Title	Durable Complete Cytogenetic Response Rate
Measure Description	Due to early termination of the trial, the number of patients was too small and imbalanced and therefore analysis was not performed.
Time Frame	24 months
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The trial was terminated early, so only 6 patients were enrolled.

Reporting Groups

	Description
Nilotinib (AMN107)	Patients received 400 mg twice daily, 2 x 200 mg capsules twice daily.
Imatinib	Patients received 400 mg twice daily. Capsules were available in 100 mg and 400 mg formulations.

Measured Values

	Nilotinib (AMN107)	Imatinib
Number of Participants Analyzed [units: participants]	**0**	**0**
Durable Complete Cytogenetic Response Rate [units: percent of participants]		

No statistical analysis provided for Durable Complete Cytogenetic Response Rate

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Nilotinib (AMN107)	Patients received 400 mg twice daily, 2 x 200 mg capsules twice daily.
Imatinib	Patients received 400 mg twice daily. Capsules were available in 100 mg and 400 mg formulations.

Serious Adverse Events

	Nilotinib (AMN107)	Imatinib
Total, serious adverse events		
# participants affected / at risk	**0/2 (0.00%)**	**0/4 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	0%

Reporting Groups

	Description
Nilotinib (AMN107)	Patients received 400 mg twice daily, 2 x 200 mg capsules twice daily.
Imatinib	Patients received 400 mg twice daily. Capsules were available in 100 mg and 400 mg formulations.

Other Adverse Events

	Nilotinib (AMN107)	Imatinib
Total, other (not including serious) adverse events		
# participants affected / at risk	**2/2 (100.00%)**	**4/4 (100.00%)**
Blood and lymphatic system disorders		
Anaemia		
# participants affected / at risk	**1/2 (50.00%)**	**0/4 (0.00%)**
Leukopenia		
# participants affected / at risk	**0/2 (0.00%)**	**1/4 (25.00%)**
Neutropenia		
# participants affected / at risk	**0/2 (0.00%)**	**1/4 (25.00%)**
Thrombocytopenia		
# participants affected / at risk	**0/2 (0.00%)**	**2/4 (50.00%)**
Eye disorders		
Periorbital Oedema		

# participants affected / at risk	0/2 (0.00%)	2/4 (50.00%)
Gastrointestinal disorders		
Constipation		
# participants affected / at risk	1/2 (50.00%)	0/4 (0.00%)
General disorders		
Fatigue		
# participants affected / at risk	1/2 (50.00%)	0/4 (0.00%)
Hepatobiliary disorders		
Hepatic function abnormality		
# participants affected / at risk	1/2 (50.00%)	0/4 (0.00%)
Hyperbilirubinemia		
# participants affected / at risk	0/2 (0.00%)	1/4 (25.00%)
Infections and infestations		
Herpes simplex		
# participants affected / at risk	0/2 (0.00%)	1/4 (25.00%)
Injury, poisoning and procedural complications		
Arthropod bite		
# participants affected / at risk	1/2 (50.00%)	0/4 (0.00%)
Metabolism and nutrition disorders		
Hypophosphataemia		
# participants affected / at risk	0/2 (0.00%)	1/4 (25.00%)
Weight decrease		
# participants affected / at risk	1/2 (50.00%)	0/4 (0.00%)
Weight increase		
# participants affected / at risk	0/2 (0.00%)	1/4 (25.00%)
Musculoskeletal and connective tissue disorders		
Muscle spasms		

# participants affected / at risk	**0/2 (0.00%)**	**2/4 (50.00%)**
Myalgia		
# participants affected / at risk	**1/2 (50.00%)**	**0/4 (0.00%)**
Nervous system disorders		
Headache		
# participants affected / at risk	**0/2 (0.00%)**	**2/4 (50.00%)**
Respiratory, thoracic and mediastinal disorders		
Cough		
# participants affected / at risk	**1/2 (50.00%)**	**0/4 (0.00%)**
Dyspnoea		
# participants affected / at risk	**1/2 (50.00%)**	**1/4 (25.00%)**
Nasopharyngitis		
# participants affected / at risk	**1/2 (50.00%)**	**1/4 (25.00%)**
Skin and subcutaneous tissue disorders		
Face Oedema		
# participants affected / at risk	**0/2 (0.00%)**	**1/4 (25.00%)**
Rash		
# participants affected / at risk	**1/2 (50.00%)**	**0/4 (0.00%)**

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. **Restriction Description:** The terms and conditions of Novartis' agreements may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data in the clinical trial.

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 862-778-8300

No publications provided by Novartis

Publications automatically indexed to this study:

Agrawal M, Hanfstein B, Erben P, Wolf D, Ernst T, Fabarius A, Saussele S, Purkayastha D, Woodman RC, Hofmann WK, Hehlmann R, Hochhaus A, Müller MC. MDR1 expression predicts outcome of Ph+ chronic phase CML patients on second-line nilotinib therapy after imatinib failure. Leukemia. 2014 Jul;28(7):1478-85. doi: 10.1038/leu.2014.6. Epub 2014 Jan 10.

Responsible Party: Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier: NCT00519090 History of Changes

Other Study ID Numbers:	**CAMN107A2302**
Study First Received:	August 17, 2007
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Last Updated:	November 4, 2011
Health Authority:	United States: Food and Drug Administration European Union: European Medicines Agency