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Trial record **1 of 1** for: CGX-635-CML-203

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Open Label Study of Subcutaneous Homoharringtonine (Omacetaxine Mepesuccinate) in Patients With Advanced CML

This study has been completed.

Sponsor:
Teva Branded Pharmaceutical Products, R&D Inc.

Collaborators:
Cephalon
ChemGenex Pharmaceuticals

Information provided by (Responsible Party):
Teva Pharmaceutical Industries (Teva Branded Pharmaceutical Products, R&D Inc.)

ClinicalTrials.gov Identifier:
NCT00462943

First received: April 17, 2007
Last updated: June 27, 2014
Last verified: June 2014
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Purpose

A Phase II open-label trial of subcutaneous HHT (omacetaxine mepesuccinate) in the treatment of patients who are resistant to or intolerant to Tyrosine Kinase Inhibitors.

Condition	Intervention	Phase
Chronic Myeloid Leukemia	Drug: Omacetaxine mepesuccinate	Phase 2

Study Type: Interventional
Study Design: Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Phase II Open-Label Study of the Subcutaneous Administration of Homoharringtonine (Omacetaxine Mepesuccinate) in the Treatment of Patients With Chronic Myeloid Leukemia (CML) Who Have Failed or Are Intolerant to Tyrosine Kinase Inhibitor Therapy

Resource links provided by NLM:

MedlinePlus related topics: Chronic Myeloid Leukemia Leukemia

Drug Information available for: Omacetaxine mepesuccinate

Genetic and Rare Diseases Information Center resources: Chronic Myeloid Leukemia Chronic Myeloproliferative Disorders Leukemia, Myeloid

U.S. FDA Resources

Further study details as provided by Teva Pharmaceutical Industries:

Primary Outcome Measures:

- Percentage of Participants Achieving an Overall Hematologic Response by Subpopulation and Total Population [Time Frame: Day 1 up to 6 months] [Designated as safety issue: No]

  Subpopulations reflect chronic myeloid leukemia (CML) phases at the time of enrollment: chronic, accelerated, and blast phase. Primary endpoints as adjudicated by the Data Monitoring Committee were used for the primary analyses.Overall hematologic response for chronic phase participants includes confirmed complete hematologic response (CHR). Overall hematologic response for accelerated or blast phase participants includes confirmed complete hematologic response (CHR), no evidence of leukemia (NEL), or return to chronic phase (RCP).

Hematologic response must last >= 8 weeks to be considered meaningful.Response rates by disease phase were examined relative to an a priori value of 2.5% using a one-sided lower 95% exact binomial confidence limit. If the lower limit from the one-sided lower 95% confidence limit exceeds 2.5%, the observed response rate will have exceeded the minimum threshold required to demonstrate efficacy.

- Percentage of Participants Achieving a Major Cytogenetic Response by Subpopulation and Total Population [Time Frame: Day 1 up to 9 months] [Designated as safety issue: No]

  Subpopulations reflect chronic myeloid leukemia (CML) phases at the time of enrollment: chronic, accelerated, and blast phase. Primary endpoints as adjudicated by the Data Monitoring Committee were used for the primary analyses.Major cytogenetic response includes complete or partial response. Both confirmed and unconfirmed major cytogenetic response is considered meaningful. Unconfirmed response is based on a single bone marrow cytogenetic evaluation for participants where a confirmatory evaluation is not available.Complete response shows 0% Philadelphia chromosome positive (Ph+) cells. A partial response shows >0% - 35% Ph+ cells.Response rates by disease phase were examined relative to an a priori value of 2.5% using a one-sided lower 95% exact binomial confidence limit. If the lower limit from the one-sided lower 95% confidence limit exceeds 2.5%, the observed response rate will have exceeded the minimum threshold required to demonstrate efficacy.

- Number of Participants With Treatment-Emergent Adverse Events (TEAEs) by Subpopulation and Total [Time Frame: up to 4 years] [Designated as safety issue: Yes]

  TEAE are any untoward events that were newly occurring or worsening from Baseline.Treatment related toxicity was considered by the investigator to be unrelated, possibly, probably or unknown related to study drug. Severity was graded according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) v3.0 on the following scale: Grade 1 = mild, Grade 2 = moderate, Grade 3 = severe, Grade 4 = life-threatening, Grade 5 = death. A serious adverse event (SAE) is any untoward medical occurrence that is fatal or life-threatening; results in persistent or significant disability or incapacity; requires or prolongs in-patient hospitalization; is a congenital anomaly/birth defect in the offspring of a patient; and conditions not included in the above that may jeopardize the patient or may require intervention to prevent one of the outcomes listed above.A participant is only counted once in each category (at worst severity or strongest relationship).

Secondary Outcome Measures:

- Percentage of Participants in Each Cytogenetic Response Category Representing the Degree of Suppression of the Philadelphia Chromosome (Ph+) [Time Frame: Day 1 up to Month 9] [Designated as safety issue: No]

  Cytogenetic response categories:

  - Complete: 0% Ph+ cells
  - Partial: >0%-35% Ph+ cells
  - Minor: >35%-65% Ph+ cells
  - Minimal: >65%-95% Ph+ cells
  - No Response: >95% Ph+ cells
  - Unevaluable: <20 metaphases were examined and/or response could not be assigned

- Percentage of Participants With Major Molecular Response (MMR) Representing the Degree of Suppression of BCR-ABL Transcript Levels Using the Housekeeping Gene GUS [Time Frame: Day 1 up to Month 6] [Designated as safety issue: No]

  MMR is defined as a ratio of BCR-ABL/standard gene of less than 0.1% according to the international scale. BCR-ABL is a fusion gene of the breakpoint cluster region [BCR] gene and Abelson proto-oncogene [ABL] genes). This analysis used the standard gene GUS. Analysis was performed by quantitative reverse transcription polymerase chain reaction (qRT-PCR) of peripheral blood.

- Percentage of Participants With Major Molecular Response (MMR) Representing the Degree of Suppression of BCR-ABL Transcript Levels Using the Housekeeping Gene ABL [Time Frame: Day 1 up to Month 6] [Designated as safety issue: No]

  MMR is defined as a ratio of BCR-ABL/standard gene of less than 0.1% according to the international scale. BCR-ABL is a fusion gene of the breakpoint cluster region [BCR] gene and Abelson proto-oncogene [ABL] genes). This analysis used the standard gene ABL. Analysis was performed by quantitative reverse transcription polymerase chain reaction (qRT-PCR) of peripheral blood.

- Percentage of Participants in Each Hematologic Response Category [Time Frame: Day 1 up to Month 6] [Designated as safety issue: No]

  Complete Response (CHR)

  - Chronic phase must last at least 8 weeks: WBC <10*10^9/liter, platelets <450*10^9/liter, myelocytes + metamyelocytes <5% in blood, no blasts or promyelocytes in blood, <20% basophils in peripheral blood, no extramedullary involvement.
  - Accelerated and Blast phase must last at least 4 weeks: absolute neutrophil count 1.5*10^9/liter, platelets 100*10^9/liter, no blood blasts, bone marrow blasts <5%, no extramedullary disease.

  Partial Response - CHR plus one or more of the following:

  - Persistence of splenomegaly with a reduction of ≥50% from pre-treatment
  - Platelets > 450*10^9/L

- Presence of immature cells in the peripheral blood
- 5% to 25% blasts in the bone marrow
- If extra-medullary disease pre-treatment, reduction by ≥50% Hematologic Improvement - CHR, except allowing persistent thrombocytopenia (<100*10^9/L), and a few immature cells No evidence of leukemia: Morphologic leukemia-free state, defined as <5% bone marrow blasts.

- Percentage of Participants With Extramedullary Disease (EMD) at Baseline Achieving a Clinical Response [Time Frame: Day 1 up to Month 9] [Designated as safety issue: No]

  Clinical response was defined by disease phase and based on evaluations by the independent Data Monitoring Committee (DMC).Chronic Phase subgroup: achieving a complete hematologic response and/or major cytogenetic response (complete cytogenetic response or partial cytogenetic response, confirmed or unconfirmed).Accelerated Phase and Blast Phase subgroups: achieving complete hematologic response, no evidence of leukemia, return to chronic phase, and/or major cytogenetic response (complete cytogenetic response or partial cytogenetic response, confirmed or unconfirmed).

- Percentage of Participants With the Largest Percentage Reduction From Baseline of T315I Mutated BCR-ABL [Time Frame: Day 1 up to Month 9] [Designated as safety issue: No]

  Summarization is based on the best of the individual response assessments. Not assessable indicates that the participant either had no baseline assessment or the % mutation could not be determined in the post-baseline assessment(s).

- Number of Treatment Cycles Needed to Achieve Best Hematologic Response [Time Frame: Day 1 up to Month 6] [Designated as safety issue: No]

  Induction therapy was administered for 14 consecutive days for each 28 days cycle, for up to 6 cycles. All treatment arms were given omacetaxine mepesuccinate via subcutaneous (SC) administration at 1.25 mg/m^2 twice a day (BID) for the 14 consecutive days.

- Number of Treatment Cycles Needed to Achieve Best Cytogenetic Response [Time Frame: Day 1 up to Month 9] [Designated as safety issue: No]
- Kaplan-Meier Estimates for Time to Onset of Best Hematologic Response [Time Frame: Day 1 up to Month 6] [Designated as safety issue: No]

  Time to onset was analyzed using Kaplan-Meier estimates. Participants who did not achieve a response are censored at their last visit day.Overall hematologic response for chronic phase participants includes confirmed complete hematologic response (CHR). Overall hematologic response for accelerated or blast phase participants includes confirmed complete hematologic response (CHR), no evidence of leukemia (NEL), or return to chronic phase (RCP). Hematologic response must last >= 8 weeks to be considered meaningful.

- Kaplan-Meier Estimates for Time to Onset of Best Cytogenetic Response [Time Frame: Day 1 up to Month 9] [Designated as safety issue: No]

  Time to onset was analyzed using Kaplan-Meier estimates. Participants who did not achieve a response are censored at their last visit day.Major cytogenetic response includes complete or partial response. Both confirmed and unconfirmed major cytogenetic response is considered meaningful. Unconfirmed response is based on a single bone marrow cytogenetic evaluation for participants where a confirmatory evaluation is not available.Complete response shows 0% Philadelphia chromosome positive (Ph+) cells. A partial response shows >0% - 35% Ph+ cells.

- Kaplan-Meier Estimates for Duration of Best Hematologic Response [Time Frame: up to four years] [Designated as safety issue: No]

  Duration of response is defined as the time from first reported date of hematologic response until the earliest date of objective evidence of disease progression, relapse or death. Data was censored at the last examination date for participants with ongoing response or participants who discontinued treatment for reasons other than adverse event, disease progression or death.

- Kaplan-Meier Estimates for Duration of Best Cytogenetic Response [Time Frame: up to four years] [Designated as safety issue: No]

  Duration of response is defined as the time from first reported date of cytogenetic response until the earliest date of objective evidence of disease progression, relapse or death. Data was censored at the last examination date for participants with ongoing response or participants who discontinued treatment for reasons other than adverse event, disease progression or death.

- Kaplan-Meier Estimates for Time to Disease Progression [Time Frame: up to 4 years] [Designated as safety issue: No]

  Time to disease progression is defined as the time from the initiation of treatment until the onset date of death, the development of CML accelerated phase or blast phase, or the loss of complete hematologic response or major cytogenetic response, whichever came first. Participants were censored only if they did not have progression or if they discontinued treatment for reasons other than AE, progression or death.

- Kaplan-Meier Estimates for Overall Survival [Time Frame: up to 4 years] [Designated as safety issue: No]

  Overall survival is defined as the time from the initiation of treatment until death from any cause or the last day of participant contact or evaluation for participants that were lost to follow-up. Participants were censored t the last recorded contract or evaluation when a participant was alive at time of analysis. A quarterly phone survey was conducted to collect survival data for participants who discontinued from the study.

Enrollment: 100
Study Start Date: March 2007
Study Completion Date: September 2013
Primary Completion Date: December 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: OMA Omacetaxine mepesuccinate (OMA) Induction: 1.25mg/m^2 subcutaneously twice daily for 14 consecutive days, every 28 days for up to six cycles. Omacetaxine mepesuccinate (OMA) Maintenance: 1.25mg/m^2 subcutaneously twice daily for 7 consecutive days, every 28 days for up to 24 months.	Drug: Omacetaxine mepesuccinate Induction: 1.25mg/m^2 subcutaneously twice daily for 14 consecutive days, every 28 days. Maintenance: 1.25mg/m^2 subcutaneously twice daily for 7 consecutive days, every 28 days. Response targets during induction vary by chronic myeloid leukemia (CML) subclass (chronic, accelerated, or blast phase). Participants will complete at least one cycle (14 days treatment of a 28 day cycle) of induction therapy before changing to maintenance therapy. Participants not demonstrating evidence of clinical response after 6 induction cycles will be considered for removal from the study. Other Names: • Homoharringtonine • HHT • Synribo • OMA • CGX-635

Detailed Description:

This will be an open label, multicenter study of subcutaneous HHT (omacetaxine mepesuccinate) therapy of patients with chronic myeloid leukemia (CML) in chronic, accelerated, or blast phase who have failed or are intolerant to tyrosine kinase inhibitor therapy. Patients will be treated with induction course cycles consisting of subcutaneous (SC) HHT 1.25 mg/m² twice daily for 14 consecutive days every 28 days. Patients will be evaluated every 7 days with complete blood and platelet counts while undergoing induction therapy; the number of consecutive doses of HHT or intervals between subsequent cycles may be adjusted, as clinically indicated, according to guidelines provided in the treatment plan.

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Male or female patients, age 18 years or older
- Philadelphia chromosome (Ph) positive chronic myelogenous leukemia in either chronic, accelerated, or blast phase
- Patients will have either failed, demonstrated intolerance, or a combination of prior failure and intolerance, to prior treatments with at least two tyrosine kinase inhibitors (TKI's). Failure of TKI treatment may either be primary (never achieved a response) or secondary resistance (loss of response).
- Acceptable Renal and Liver Function
- Eastern Cooperative Oncology Group (ECOG) performance status 0-2.
- Sexually active patients and their partners must use an effective double barrier method of contraception

Exclusion Criteria:

- New York Heart Association classification (NYHA) class III or IV heart disease, active ischemia or any other uncontrolled cardiac condition
- Myocardial infarction in the previous 12 weeks.
- Other concurrent illness which would preclude study conduct and assessment
- uncontrolled and active infection, and positive HIV or positive HTLV I/II status, whether on treatment or not.
- Pregnant or lactating.
- Any medical or psychiatric condition, which may compromise the ability to give written informed consent or to comply with the study protocol.
- Lymphoid Ph+ blast crisis
- Patient is enrolled in another clinical investigation within 30 days of enrollment or is receiving another investigational agent

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00462943

Hide Study Locations

Locations

United States, California

Teva Investigational Site 303
Los Angeles, California, United States

United States, Indiana

Teva Investigational Site 308
Beech Grove, Indiana, United States

United States, Maryland

Teva Investigational Site 311
Baltimore, Maryland, United States

United States, New York

Teva Investigational Site 302
Bronx, New York, United States

Teva Investigational Site 305
Buffalo, New York, United States

United States, Pennsylvania

Teva Investigational Site 310
Philadelphia, Pennsylvania, United States

United States, Texas

Teva Investigational Site 301
Houston, Texas, United States

United States, Washington

Teva Investigational Site 314
Seattle, Washington, United States

Canada

Teva Investigational Site 313
Montreal, Canada

Teva Investigational Site 309
Toronto, Canada

France

Teva Investigational Site 329
Bordeaux, France

Teva Investigational Site 321
Le Chesnay Cedex, France

Teva Investigational Site 322
Lille, France

Teva Investigational Site 320
Lyon Cedex 03, France

Teva Investigational Site 324
Nice, France

Teva Investigational Site 328
Paris, France

Teva Investigational Site 323
Poitiers Cedex, France

Teva Investigational Site 327
Strasbourg, France

Teva Investigational Site 325
Toulouse, France

Germany

Teva Investigational Site 331
Berlin, Germany

Teva Investigational Site 330
Mannheim, Germany

Hungary

Teva Investigational Site 350
Budapest, Hungary

India

Teva Investigational Site 371
Hyderabad, India

Teva Investigational Site 370
Mumbai, India

Italy

Teva Investigational Site 390
Bologna, Italy

Poland

Teva Investigational Site 360
Gdansk, Poland

Singapore

Teva Investigational Site 380
Singapore, Singapore

United Kingdom

Teva Investigational Site 340
London, United Kingdom

Sponsors and Collaborators

Teva Branded Pharmaceutical Products, R&D Inc.

Cephalon

ChemGenex Pharmaceuticals

Investigators

Principal Investigator: Jorge Cortes, MD M.D. Anderson Cancer Center

More Information

No publications provided by Teva Pharmaceutical Industries

Additional publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Cortes J, Digumarti R, Parikh PM, Wetzler M, Lipton JH, Hochhaus A, Craig AR, Benichou AC, Nicolini FE, Kantarjian HM; Omacetaxine 203 Study Group. Phase 2 study of subcutaneous omacetaxine mepesuccinate for chronic-phase chronic myeloid leukemia patients resistant to or intolerant of tyrosine kinase inhibitors. Am J Hematol. 2013 May;88(5):350-4. doi: 10.1002/ajh.23408. Epub 2013 Mar 7.

Responsible Party:	Teva Pharmaceutical Industries (Teva Branded Pharmaceutical Products, R&D Inc.)
ClinicalTrials.gov Identifier:	NCT00462943 History of Changes
Other Study ID Numbers:	**CGX-635-CML-203**, 2007-001286-15
Study First Received:	April 17, 2007
Results First Received:	May 5, 2014
Last Updated:	June 27, 2014
Health Authority:	United States: Food and Drug Administration Canada: Health Canada European Union: European Medicines Agency United Kingdom: Medicines and Healthcare Products Regulatory Agency India: Drugs Controller General of India Singapore: Health Sciences Authority

Keywords provided by Teva Pharmaceutical Industries:
CML
HHT
Homoharringtonine
Omacetaxine

Additional relevant MeSH terms:

Leukemia, Myelogenous, Chronic, BCR-ABL Positive	Angiogenesis Inhibitors
Leukemia, Myeloid	Angiogenesis Modulating Agents
Bone Marrow Diseases	Antineoplastic Agents
Hematologic Diseases	Antineoplastic Agents, Phytogenic
Leukemia	Growth Inhibitors
Myeloproliferative Disorders	Growth Substances
Neoplasms	Pharmacologic Actions
Neoplasms by Histologic Type	Physiological Effects of Drugs
Harringtonines	Therapeutic Uses
Homoharringtonine	

ClinicalTrials.gov processed this record on August 18, 2015

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Trial record **1 of 1** for: CGX-635-CML-203

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Open Label Study of Subcutaneous Homoharringtonine (Omacetaxine Mepesuccinate) in Patients With Advanced CML

This study has been completed.

Sponsor:
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Collaborators:
Cephalon
ChemGenex Pharmaceuticals

Information provided by (Responsible Party):
Teva Pharmaceutical Industries (Teva Branded Pharmaceutical Products, R&D Inc.)

ClinicalTrials.gov Identifier:
NCT00462943

First received: April 17, 2007
Last updated: June 27, 2014
Last verified: June 2014
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: May 5, 2014

Study Type:	Interventional
Study Design:	Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Chronic Myeloid Leukemia
Intervention:	Drug: Omacetaxine mepesuccinate

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
CML: Chronic Phase	Study participants with chronic myeloid leukemia (CML) in the chronic phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Accelerated Phase	Study participants with chronic myeloid leukemia (CML) in the accelerated phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles.

	Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Blast Phase	Study participants with chronic myeloid leukemia (CML) in the blast phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.

Participant Flow: Overall Study

	CML: Chronic Phase	CML: Accelerated Phase	CML: Blast Phase
STARTED	46	31	23
COMPLETED	1	1	0
NOT COMPLETED	45	30	23
Failure to achieve a response	5	5	1
Adverse Event	6	4	1
Protocol Violation	1	0	0
Request of Patient, PI, Sponsor or RA	8	2	4
Disease Progression	15	15	9
Death	5	2	7
Stem Cell Transplant	1	1	0
Bone Marrow Transplant	1	0	0
Required Lymphocyte Infusion	1	0	0
Transplant - not specified	1	0	1
Physician Decision	1	0	0
Withdrawal by Subject	0	1	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.
Intent to Treat Population: all participants who provided written informed consent and received at least 1 dose of study drug constitute the ITT population.

Reporting Groups

	Description
CML: Chronic Phase	Study participants with chronic myeloid leukemia (CML) in the chronic phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Accelerated Phase	Study participants with chronic myeloid leukemia (CML) in the accelerated phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Blast Phase	Study participants with chronic myeloid leukemia (CML) in the blast phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2

	twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
Total	Total of all reporting groups

Baseline Measures

	CML: Chronic Phase	CML: Accelerated Phase	CML: Blast Phase	Total
Number of Participants [units: participants]	**46**	**31**	**23**	**100**
Age [units: years] Median (Full Range)	**58 (20 to 78)**	**56 (23 to 71)**	**57 (30 to 68)**	**57 (20 to 78)**
Gender [units: participants]				
Female	**20**	**12**	**9**	**41**
Male	**26**	**19**	**14**	**59**
Race/Ethnicity, Customized [units: participants]				
Caucasian	**31**	**17**	**12**	**60**
Black	**2**	**4**	**5**	**11**
Hispanic	**3**	**2**	**1**	**6**
Asian	**7**	**7**	**4**	**18**
Other	**3**	**1**	**1**	**5**
Height [units: centimeter] Median (Full Range)	**167.7 (155.0 to 188.0)**	**167.5 (148.0 to 195.0)**	**171.0 (149.9 to 191.0)**	**167.6 (148.0 to 195.0)**
Weight [units: kilograms] Median (Full Range)	**79.5 (40.0 to 138.0)**	**67.4 (36.5 to 111.8)**	**74.0 (41.0 to 136.4)**	**74.2 (36.5 to 138.0)**
Body Surface Area (BSA) [units: meters^2] Median (Full Range)	**1.9 (1.3 to 2.5)**	**1.7 (1.4 to 2.2)**	**1.9 (1.4 to 2.5)**	**1.9 (1.3 to 2.5)**
New York Heart Association (NYHA) Classification [1] [units: participants]				
Class I	**44**	**29**	**23**	**96**
Class II	**2**	**0**	**0**	**2**
Class III	**0**	**0**	**0**	**0**
Class IV	**0**	**0**	**0**	**0**
Not available	**0**	**2**	**0**	**2**
Eastern Cooperative Oncology Group Performance Status [2] [units: participants]				
Grade 0	**27**	**7**	**6**	**40**
Grade 1	**17**	**19**	**11**	**47**
Grade 2	**2**	**5**	**5**	**12**
Grade 3	**0**	**0**	**1**	**1**

Time from Initial Chronic Myeloid Leukemia (CML) Diagnosis [units: months] Median (Full Range)	**74.4 (7.9 to 221.0)**	**83.5 (20.3 to 197.1)**	**68.7 (6.6 to 195.5)**	**74.0 (6.6 to 221.0)**

[1]
- Class I: Cardiac disease, but no symptoms and no limitation in ordinary physical activity, e.g. shortness of breath when walking, climbing stairs etc.
- Class II: Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
- Class III: Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g. walking short distances (20–100 m). Comfortable only at rest.
- Class IV: Severe limitations. Experiences symptoms even while at rest. Mostly bed-bound patients.

[2]
- Grade 0: Fully active, able to carry on all pre-disease activities without restriction;
- Grade 1: Restricted in physically strenuous activity, ambulatory and able to carry out work of a light nature;
- Grade 2: Ambulatory and capable of all self-care but unable to work. Up and about more than 50% of waking hours;
- Grade 3: Capable of only limited self-care, confined to bed or chair > 50% of waking hours;
- Grade 4: Completely disabled. Cannot carry on any self-care. Confined to bed or chair.

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants Achieving an Overall Hematologic Response by Subpopulation and Total Population [Time Frame: Day 1 up to 6 months]

Measure Type	Primary
Measure Title	Percentage of Participants Achieving an Overall Hematologic Response by Subpopulation and Total Population
Measure Description	Subpopulations reflect chronic myeloid leukemia (CML) phases at the time of enrollment: chronic, accelerated, and blast phase. Primary endpoints as adjudicated by the Data Monitoring Committee were used for the primary analyses. Overall hematologic response for chronic phase participants includes confirmed complete hematologic response (CHR). Overall hematologic response for accelerated or blast phase participants includes confirmed complete hematologic response (CHR), no evidence of leukemia (NEL), or return to chronic phase (RCP). Hematologic response must last >= 8 weeks to be considered meaningful. Response rates by disease phase were examined relative to an a priori value of 2.5% using a one-sided lower 95% exact binomial confidence limit. If the lower limit from the one-sided lower 95% confidence limit exceeds 2.5%, the observed response rate will have exceeded the minimum threshold required to demonstrate efficacy.
Time Frame	Day 1 up to 6 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.
Intent to treat population

Reporting Groups

	Description
CML: Chronic Phase	Study participants with chronic myeloid leukemia (CML) in the chronic phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Accelerated Phase	Study participants with chronic myeloid leukemia (CML) in the accelerated phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles.

	Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Blast Phase	Study participants with chronic myeloid leukemia (CML) in the blast phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
Total Participants	Treatment included induction therapy of subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.

Measured Values

	CML: Chronic Phase	CML: Accelerated Phase	CML: Blast Phase	Total Participants
Number of Participants Analyzed [units: participants]	**46**	**31**	**23**	**100**
Percentage of Participants Achieving an Overall Hematologic Response by Subpopulation and Total Population [units: percentage of participants] Number (95% Confidence Interval)	**67.4 (51.98 to NA) [1]**	**25.8 (11.86 to NA) [1]**	**8.7 (1.07 to NA) [1]**	**41.0 (31.26 to NA) [1]**

[1] Lower limit of the 2-sided 95% CI is reported

No statistical analysis provided for Percentage of Participants Achieving an Overall Hematologic Response by Subpopulation and Total Population

2. Primary: Percentage of Participants Achieving a Major Cytogenetic Response by Subpopulation and Total Population [Time Frame: Day 1 up to 9 months]

Measure Type	Primary
Measure Title	Percentage of Participants Achieving a Major Cytogenetic Response by Subpopulation and Total Population
Measure Description	Subpopulations reflect chronic myeloid leukemia (CML) phases at the time of enrollment: chronic, accelerated, and blast phase. Primary endpoints as adjudicated by the Data Monitoring Committee were used for the primary analyses. Major cytogenetic response includes complete or partial response. Both confirmed and unconfirmed major cytogenetic response is considered meaningful. Unconfirmed response is based on a single bone marrow cytogenetic evaluation for participants where a confirmatory evaluation is not available. Complete response shows 0% Philadelphia chromosome positive (Ph+) cells. A partial response shows >0% - 35% Ph+ cells. Response rates by disease phase were examined relative to an a priori value of 2.5% using a one-sided lower 95% exact binomial confidence limit. If the lower limit from the one-sided lower 95% confidence limit exceeds 2.5%, the observed response rate will have exceeded the minimum threshold required to demonstrate efficacy.
Time Frame	Day 1 up to 9 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.
Intent to treat population

Reporting Groups

	Description

CML: Chronic Phase	Study participants with chronic myeloid leukemia (CML) in the chronic phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Accelerated Phase	Study participants with chronic myeloid leukemia (CML) in the accelerated phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Blast Phase	Study participants with chronic myeloid leukemia (CML) in the blast phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
Total Participants	Treatment included induction therapy of subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.

Measured Values

	CML: Chronic Phase	CML: Accelerated Phase	CML: Blast Phase	Total Participants
Number of Participants Analyzed [units: participants]	**46**	**31**	**23**	**100**
Percentage of Participants Achieving a Major Cytogenetic Response by Subpopulation and Total Population [units: percentage of participants] Number (95% Confidence Interval)	**21.7 (10.95 to NA)** [1]	**3.2 (0.08 to NA)** [1]	**0 (0 to NA)** [1]	**11 (5.62 to NA)** [1]

[1] Lower limit of the 2-sided 95% CI is reported

No statistical analysis provided for Percentage of Participants Achieving a Major Cytogenetic Response by Subpopulation and Total Population

3. Primary: Number of Participants With Treatment-Emergent Adverse Events (TEAEs) by Subpopulation and Total [Time Frame: up to 4 years]

Measure Type	Primary
Measure Title	Number of Participants With Treatment-Emergent Adverse Events (TEAEs) by Subpopulation and Total
Measure Description	TEAE are any untoward events that were newly occurring or worsening from Baseline. Treatment related toxicity was considered by the investigator to be unrelated, possibly, probably or unknown related to study drug. Severity was graded according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) v3.0 on the following scale: Grade 1 = mild, Grade 2 = moderate, Grade 3 = severe, Grade 4 = life-threatening, Grade 5 = death. A serious adverse event (SAE) is any untoward medical occurrence that is fatal or life-threatening; results in persistent or significant disability or incapacity; requires or prolongs in-patient hospitalization; is a congenital anomaly/birth defect in the offspring of a patient; and conditions not included in the above that may jeopardize the patient or may require intervention to prevent one of the outcomes listed above. A participant is only counted once in each category (at worst severity or strongest relationship).
Time Frame	up to 4 years
Safety Issue	Yes

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.

Intent to treat

Reporting Groups

	Description
CML: Chronic Phase	Study participants with chronic myeloid leukemia (CML) in the chronic phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Accelerated Phase	Study participants with chronic myeloid leukemia (CML) in the accelerated phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Blast Phase	Study participants with chronic myeloid leukemia (CML) in the blast phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
Total Participants	Treatment included induction therapy of subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.

Measured Values

	CML: Chronic Phase	CML: Accelerated Phase	CML: Blast Phase	Total Participants
Number of Participants Analyzed [units: participants]	**46**	**31**	**23**	**100**
Number of Participants With Treatment-Emergent Adverse Events (TEAEs) by Subpopulation and Total [units: participants]				
>=1 TEAE	**46**	**31**	**23**	**100**
>= 1 SAE	**26**	**19**	**18**	**63**
Worst severity: Grade 1	**1**	**0**	**0**	**1**
Worst severity: Grade 2	**4**	**4**	**2**	**10**
Worst severity: Grade 3	**18**	**6**	**4**	**28**
Worst severity: Grade 4	**17**	**15**	**6**	**38**
Worst severity: Grade 5	**6**	**6**	**11**	**23**
Relation to drug: Unrelated	**4**	**4**	**7**	**15**
Relation to drug: Possibly	**5**	**11**	**7**	**23**
Relation to drug: Probably	**36**	**14**	**8**	**58**
Relation to drug: Unknown	**1**	**2**	**1**	**4**
With hematologic toxicity	**36**	**22**	**13**	**71**
Discontinued treatment due to AE	**10**	**11**	**6**	**27**
Deaths during study or follow-up	**35**	**25**	**21**	**71**
Deaths during study (outcome of SAE)	**6**	**6**	**11**	**23**

No statistical analysis provided for Number of Participants With Treatment-Emergent Adverse Events (TEAEs) by Subpopulation and Total

4. Secondary: Percentage of Participants in Each Cytogenetic Response Category Representing the Degree of Suppression of the Philadelphia Chromosome (Ph+) [Time Frame: Day 1 up to Month 9]

Measure Type	Secondary
Measure Title	Percentage of Participants in Each Cytogenetic Response Category Representing the Degree of Suppression of the Philadelphia Chromosome (Ph+)
Measure Description	Cytogenetic response categories: • Complete: 0% Ph+ cells • Partial: >0%-35% Ph+ cells • Minor: >35%-65% Ph+ cells • Minimal: >65%-95% Ph+ cells • No Response: >95% Ph+ cells • Unevaluable: <20 metaphases were examined and/or response could not be assigned
Time Frame	Day 1 up to Month 9
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.
Intent to treat

Reporting Groups

	Description
CML: Chronic Phase	Study participants with chronic myeloid leukemia (CML) in the chronic phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Accelerated Phase	Study participants with chronic myeloid leukemia (CML) in the accelerated phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Blast Phase	Study participants with chronic myeloid leukemia (CML) in the blast phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
Total Participants	Treatment included induction therapy of subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.

Measured Values

	CML: Chronic Phase	**CML: Accelerated Phase**	**CML: Blast Phase**	**Total Participants**
Number of Participants Analyzed [units: participants]	**46**	**31**	**23**	**100**
Percentage of Participants in Each Cytogenetic Response Category Representing the Degree of Suppression of the Philadelphia Chromosome (Ph+) [units: percentage of participants]				

Complete	**4.3**	**0**	**0**	**2.0**
Partial	**17.4**	**3.2**	**0**	**9.0**
Minor	**8.7**	**9.7**	**0**	**7.0**
Minimal	**6.5**	**6.5**	**4.3**	**6.0**
No Response	**39.1**	**61.3**	**30.4**	**44.0**
Unevaluable	**23.9**	**19.4**	**65.2**	**32.0**

No statistical analysis provided for Percentage of Participants in Each Cytogenetic Response Category Representing the Degree of Suppression of the Philadelphia Chromosome (Ph+)

5. Secondary: Percentage of Participants With Major Molecular Response (MMR) Representing the Degree of Suppression of BCR-ABL Transcript Levels Using the Housekeeping Gene GUS [Time Frame: Day 1 up to Month 6]

Measure Type	Secondary
Measure Title	Percentage of Participants With Major Molecular Response (MMR) Representing the Degree of Suppression of BCR-ABL Transcript Levels Using the Housekeeping Gene GUS
Measure Description	MMR is defined as a ratio of BCR-ABL/standard gene of less than 0.1% according to the international scale. BCR-ABL is a fusion gene of the breakpoint cluster region [BCR] gene and Abelson proto-oncogene [ABL] genes). This analysis used the standard gene GUS. Analysis was performed by quantitative reverse transcription polymerase chain reaction (qRT-PCR) of peripheral blood.
Time Frame	Day 1 up to Month 6
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.
Intent to treat population of participants who had evaluable samples. Participants with no data for these analyses either had degraded samples or the samples were missing.

Reporting Groups

	Description
CML: Chronic Phase	Study participants chronic myeloid leukemia (CML) in the chronic phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Accelerated Phase	Study participants with chronic myeloid leukemia (CML) in the accelerated phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Blast Phase	Study participants with chronic myeloid leukemia (CML) in the blast phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
Total Participants	Treatment included induction therapy of subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.

Measured Values

	CML: Chronic Phase	CML: Accelerated Phase	CML: Blast Phase	Total Participants
Number of Participants Analyzed [units: participants]	**22**	**18**	**4**	**44**
Percentage of Participants With Major Molecular Response (MMR) Representing the Degree of Suppression of BCR-ABL Transcript Levels Using the Housekeeping Gene GUS [units: percentage of participants] Number (95% Confidence Interval)	**13.6 (2.9 to 34.9)**	**0 (NA to NA) [1]**	**0 (NA to NA) [1]**	**6.8 (1.4 to 18.7)**

[1] no participants met criteria

No statistical analysis provided for Percentage of Participants With Major Molecular Response (MMR) Representing the Degree of Suppression of BCR-ABL Transcript Levels Using the Housekeeping Gene GUS

6. Secondary: Percentage of Participants With Major Molecular Response (MMR) Representing the Degree of Suppression of BCR-ABL Transcript Levels Using the Housekeeping Gene ABL [Time Frame: Day 1 up to Month 6]

Measure Type	Secondary
Measure Title	Percentage of Participants With Major Molecular Response (MMR) Representing the Degree of Suppression of BCR-ABL Transcript Levels Using the Housekeeping Gene ABL
Measure Description	MMR is defined as a ratio of BCR-ABL/standard gene of less than 0.1% according to the international scale. BCR-ABL is a fusion gene of the breakpoint cluster region [BCR] gene and Abelson proto-oncogene [ABL] genes). This analysis used the standard gene ABL. Analysis was performed by quantitative reverse transcription polymerase chain reaction (qRT-PCR) of peripheral blood.
Time Frame	Day 1 up to Month 6
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.
Intent to treat population of participants who had evaluable samples. Participants with no data for these analyses either had degraded samples or the samples were missing.

Reporting Groups

	Description
CML: Chronic Phase	Study participants with chronic myeloid leukemia (CML) in the chronic phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Accelerated Phase	Study participants with chronic myeloid leukemia (CML) in the accelerated phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Blast Phase	Study participants with chronic myeloid leukemia (CML) in the blast phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
Total Participants	Treatment included induction therapy of subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was

	subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.

Measured Values

	CML: Chronic Phase	CML: Accelerated Phase	CML: Blast Phase	Total Participants
Number of Participants Analyzed [units: participants]	**38**	**23**	**11**	**72**
Percentage of Participants With Major Molecular Response (MMR) Representing the Degree of Suppression of BCR-ABL Transcript Levels Using the Housekeeping Gene ABL [units: percentage of participants] Number (95% Confidence Interval)	**10.5 (2.9 to 24.8)**	**4.3 (0.1 to 22.0)**	**0 (NA to NA) [1]**	**6.9 (2.3 to 15.5)**

[1] no participants met criteria

No statistical analysis provided for Percentage of Participants With Major Molecular Response (MMR) Representing the Degree of Suppression of BCR-ABL Transcript Levels Using the Housekeeping Gene ABL

7. Secondary: Percentage of Participants in Each Hematologic Response Category [Time Frame: Day 1 up to Month 6]

Measure Type	Secondary
Measure Title	Percentage of Participants in Each Hematologic Response Category
Measure Description	Complete Response (CHR) • Chronic phase must last at least 8 weeks: WBC <10*10^9/liter, platelets <450*10^9/liter, myelocytes + metamyelocytes <5% in blood, no blasts or promyelocytes in blood, <20% basophils in peripheral blood, no extramedullary involvement. • Accelerated and Blast phase must last at least 4 weeks: absolute neutrophil count 1.5*10^9/liter, platelets 100*10^9/liter, no blood blasts, bone marrow blasts <5%, no extramedullary disease. Partial Response - CHR plus one or more of the following: • Persistence of splenomegaly with a reduction of ≥50% from pre-treatment • Platelets > 450*10^9/L • Presence of immature cells in the peripheral blood • 5% to 25% blasts in the bone marrow • If extra-medullary disease pre-treatment, reduction by ≥50% Hematologic Improvement - CHR, except allowing persistent thrombocytopenia (<100*10^9/L), and a few immature cells No evidence of leukemia: Morphologic leukemia-free state, defined as <5% bone marrow blasts.
Time Frame	Day 1 up to Month 6
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.
Intent to treat

Reporting Groups

	Description
CML: Chronic Phase	Study participants with chronic myeloid leukemia (CML) in the chronic phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.

CML: Accelerated Phase	Study participants with chronic myeloid leukemia (CML) in the accelerated phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Blast Phase	Study participants with chronic myeloid leukemia (CML) in the blast phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
Total Participants	Treatment included induction therapy of subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.

Measured Values

	CML: Chronic Phase	CML: Accelerated Phase	CML: Blast Phase	Total Participants
Number of Participants Analyzed [units: participants]	**46**	**31**	**23**	**100**
Percentage of Participants in Each Hematologic Response Category [units: percentage of participants]				
Complete response	**67.4**	**19.4**	**8.7**	**39.0**
Partial response	**0**	**3.2**	**0**	**1.0**
Hematologic improvement	**0**	**9.7**	**4.3**	**4.0**
Return to chronic phase	**NA** [1]	**6.5**	**0**	**2.0**
No evidence of leukemia	**NA** [2]	**0**	**0**	**0**
No response	**21.7**	**58.1**	**78.3**	**46.0**
Unevaluable	**10.9**	**3.2**	**8.7**	**8.0**

[1] Participants enrolled in chronic phase and therefore cannot respond (improve) to chronic phase.
[2] An overall hematologic response for chronic phase participants only included a complete hematologic response.

No statistical analysis provided for Percentage of Participants in Each Hematologic Response Category

8. Secondary: Percentage of Participants With Extramedullary Disease (EMD) at Baseline Achieving a Clinical Response [Time Frame: Day 1 up to Month 9]

Measure Type	Secondary
Measure Title	Percentage of Participants With Extramedullary Disease (EMD) at Baseline Achieving a Clinical Response
Measure Description	Clinical response was defined by disease phase and based on evaluations by the independent Data Monitoring Committee (DMC). Chronic Phase subgroup: achieving a complete hematologic response and/or major cytogenetic response (complete cytogenetic response or partial cytogenetic response, confirmed or unconfirmed). Accelerated Phase and Blast Phase subgroups: achieving complete hematologic response, no evidence of leukemia, return to chronic phase, and/or major cytogenetic response (complete cytogenetic response or partial cytogenetic response, confirmed or unconfirmed).
Time Frame	Day 1 up to Month 9
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.
Intent to treat population of study participants who had extramedullary disease at baseline

Reporting Groups

	Description
CML: Chronic Phase	Study participants with chronic myeloid leukemia (CML) in the chronic phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Accelerated Phase	Study participants with chronic myeloid leukemia (CML) in the accelerated phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Blast Phase	Study participants with chronic myeloid leukemia (CML) in the blast phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.

Measured Values

	CML: Chronic Phase	CML: Accelerated Phase	CML: Blast Phase
Number of Participants Analyzed [units: participants]	**0**	**0**	**2**
Percentage of Participants With Extramedullary Disease (EMD) at Baseline Achieving a Clinical Response [units: percentage of participants]			
Clinical response			**0**
Unevaluable			**50**

No statistical analysis provided for Percentage of Participants With Extramedullary Disease (EMD) at Baseline Achieving a Clinical Response

9. Secondary: Percentage of Participants With the Largest Percentage Reduction From Baseline of T315I Mutated BCR-ABL [Time Frame: Day 1 up to Month 9]

Measure Type	Secondary
Measure Title	Percentage of Participants With the Largest Percentage Reduction From Baseline of T315I Mutated BCR-ABL
Measure Description	Summarization is based on the best of the individual response assessments. Not assessable indicates that the participant either had no baseline assessment or the % mutation could not be determined in the post-baseline assessment(s).
Time Frame	Day 1 up to Month 9
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.
Intent to treat population of participants with post-baseline assessment of T315I mutated BCR ABL

Reporting Groups

	Description
CML: Chronic Phase	Study participants with chronic myeloid leukemia (CML) in the chronic phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Accelerated Phase	Study participants with chronic myeloid leukemia (CML) in the accelerated phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Blast Phase	Study participants with chronic myeloid leukemia (CML) in the blast phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
Total Participants	Treatment included induction therapy of subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.

Measured Values

	CML: Chronic Phase	CML: Accelerated Phase	CML: Blast Phase	Total Participants
Number of Participants Analyzed [units: participants]	**38**	**23**	**11**	**72**
Percentage of Participants With the Largest Percentage Reduction From Baseline of T315I Mutated BCR-ABL [units: percentage of participants] Number (95% Confidence Interval)				
100% reduction	**0 (0 to 0)**	**0 (0 to 0)**	**0 (0 to 0)**	**0 (0 to 0)**
75-99% reduction	**0 (0 to 0)**	**0 (0 to 0)**	**0 (0 to 0)**	**0 (0 to 0)**
50-74% reduction	**0 (0 to 0)**	**0 (0 to 0)**	**0 (0 to 0)**	**0 (0 to 0)**
25-49% reduction	**0 (0 to 0)**	**0 (0 to 0)**	**9.1 (0.3 to 52.7)**	**1.4 (0.0 to 9.1)**
1-24% reduction	**0 (0 to 0)**	**0 (0 to 0)**	**0 (0 to 0)**	**0 (0 to 0)**
0% reduction	**78.9 (76.4 to 100)**	**91.3 (83.9 to 100)**	**63.3 (47.4 to 99.7)**	**80.6 (79.9 to 100)**
Not assessable	**21.1 (NA to NA) [1]**	**8.7 (NA to NA) [1]**	**27.3 (NA to NA) [1]**	**18.1 (NA to NA) [1]**

[1] 95% CI not calculated for a non-response category.

No statistical analysis provided for Percentage of Participants With the Largest Percentage Reduction From Baseline of T315I Mutated BCR-ABL

10. Secondary: Number of Treatment Cycles Needed to Achieve Best Hematologic Response [Time Frame: Day 1 up to Month 6]

Measure Type	Secondary
Measure Title	Number of Treatment Cycles Needed to Achieve Best Hematologic Response

Measure Description	Induction therapy was administered for 14 consecutive days for each 28 days cycle, for up to 6 cycles. All treatment arms were given omacetaxine mepesuccinate via subcutaneous (SC) administration at 1.25 mg/m^2 twice a day (BID) for the 14 consecutive days.
Time Frame	Day 1 up to Month 6
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.
Intent to treat population of participants who had a response to treatment

Reporting Groups

	Description
CML: Chronic Phase	Study participants with chronic myeloid leukemia (CML) in the chronic phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Accelerated Phase	Study participants with chronic myeloid leukemia (CML) in the accelerated phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Blast Phase	Study participants with chronic myeloid leukemia (CML) in the blast phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
Total Participants	Treatment included induction therapy of subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.

Measured Values

	CML: Chronic Phase	**CML: Accelerated Phase**	**CML: Blast Phase**	**Total Participants**
Number of Participants Analyzed [units: participants]	**31**	**8**	**2**	**41**
Number of Treatment Cycles Needed to Achieve Best Hematologic Response [units: treatment cycles] Median (Full Range)	**1.0 (1 to 5)**	**2.0 (1 to 4)**	**2.0 (1 to 3)**	**1.0 (1 to 5)**

No statistical analysis provided for Number of Treatment Cycles Needed to Achieve Best Hematologic Response

11. Secondary: Number of Treatment Cycles Needed to Achieve Best Cytogenetic Response [Time Frame: Day 1 up to Month 9]

Measure Type	Secondary
Measure Title	Number of Treatment Cycles Needed to Achieve Best Cytogenetic Response
Measure Description	No text entered.
Time Frame	Day 1 up to Month 9
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.
Intent to treat population of participants who had a cytogenetic response

Reporting Groups

	Description
CML: Chronic Phase	Study participants with chronic myeloid leukemia (CML) in the chronic phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Accelerated Phase	Study participants with chronic myeloid leukemia (CML) in the accelerated phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Blast Phase	Study participants with chronic myeloid leukemia (CML) in the blast phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
Total Participants	Treatment included induction therapy of subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.

Measured Values

	CML: Chronic Phase	**CML: Accelerated Phase**	**CML: Blast Phase**	**Total Participants**
Number of Participants Analyzed [units: participants]	**17**	**6**	**1**	**24**
Number of Treatment Cycles Needed to Achieve Best Cytogenetic Response [units: treatment cycles] Median (Full Range)	**2.0 (1 to 9)**	**1.5 (1 to 4)**	**1.0 (1 to 1)**	**2.0 (1 to 9)**

No statistical analysis provided for Number of Treatment Cycles Needed to Achieve Best Cytogenetic Response

12. Secondary: Kaplan-Meier Estimates for Time to Onset of Best Hematologic Response [Time Frame: Day 1 up to Month 6]

Measure Type	Secondary
Measure Title	Kaplan-Meier Estimates for Time to Onset of Best Hematologic Response
Measure Description	Time to onset was analyzed using Kaplan-Meier estimates. Participants who did not achieve a response are censored at their last visit day. Overall hematologic response for chronic phase participants includes confirmed complete hematologic response (CHR). Overall hematologic response for accelerated or blast phase participants includes confirmed complete hematologic response (CHR), no evidence of leukemia (NEL), or return to chronic phase (RCP). Hematologic response must last >= 8 weeks to be considered meaningful.
Time Frame	Day 1 up to Month 6
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.
Intent to treat population.

Reporting Groups

	Description
CML: Chronic Phase	Study participants with chronic myeloid leukemia (CML) in the chronic phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Accelerated Phase	Study participants with chronic myeloid leukemia (CML) in the accelerated phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Blast Phase	Study participants with chronic myeloid leukemia (CML) in the blast phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
Total Participants	Treatment included induction therapy of subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.

Measured Values

	CML: Chronic Phase	**CML: Accelerated Phase**	**CML: Blast Phase**	**Total Participants**
Number of Participants Analyzed [units: participants]	**46**	**31**	**23**	**100**
Kaplan-Meier Estimates for Time to Onset of Best Hematologic Response [units: months] Median (95% Confidence Interval)	**1.38 (0.49 to 1.84)**	**NA (4.14 to NA)** [1]	**NA (NA to NA)** [1]	**5.03 (3.13 to NA)** [1]

[1] A large percentage of participants were censored.

No statistical analysis provided for Kaplan-Meier Estimates for Time to Onset of Best Hematologic Response

13. Secondary: Kaplan-Meier Estimates for Time to Onset of Best Cytogenetic Response [Time Frame: Day 1 up to Month 9]

Measure Type	Secondary
Measure Title	Kaplan-Meier Estimates for Time to Onset of Best Cytogenetic Response
Measure Description	Time to onset was analyzed using Kaplan-Meier estimates. Participants who did not achieve a response are censored at their last visit day. Major cytogenetic response includes complete or partial response. Both confirmed and unconfirmed major cytogenetic response is considered meaningful. Unconfirmed response is based on a single bone marrow cytogenetic evaluation for participants where a confirmatory evaluation is not available. Complete response shows 0% Philadelphia chromosome positive (Ph+) cells. A partial response shows >0% - 35% Ph+ cells.
Time Frame	Day 1 up to Month 9

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.
Intent to treat population.

Reporting Groups

	Description
CML: Chronic Phase	Study participants with chronic myeloid leukemia (CML) in the chronic phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Accelerated Phase	Study participants with chronic myeloid leukemia (CML) in the accelerated phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Blast Phase	Study participants with chronic myeloid leukemia (CML) in the blast phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.

Measured Values

	CML: Chronic Phase	**CML: Accelerated Phase**	**CML: Blast Phase**
Number of Participants Analyzed [units: participants]	**46**	**31**	**23**
Kaplan-Meier Estimates for Time to Onset of Best Cytogenetic Response [units: months] Median (95% Confidence Interval)	**NA (NA to NA)** [1]	**NA (NA to NA)** [1]	**NA (NA to NA)** [1]

[1] A large percentage of participants were censored.

No statistical analysis provided for Kaplan-Meier Estimates for Time to Onset of Best Cytogenetic Response

14. Secondary: Kaplan-Meier Estimates for Duration of Best Hematologic Response [Time Frame: up to four years]

Measure Type	Secondary
Measure Title	Kaplan-Meier Estimates for Duration of Best Hematologic Response
Measure Description	Duration of response is defined as the time from first reported date of hematologic response until the earliest date of objective evidence of disease progression, relapse or death. Data was censored at the last examination date for participants with ongoing response or participants who discontinued treatment for reasons other than adverse event, disease progression or death.
Time Frame	up to four years
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.

Intent to treat population of participants who had a response

Reporting Groups

	Description
CML: Chronic Phase	Study participants with chronic myeloid leukemia (CML) in the chronic phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Accelerated Phase	Study participants with chronic myeloid leukemia (CML) in the accelerated phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Blast Phase	Study participants with chronic myeloid leukemia (CML) in the blast phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.

Measured Values

	CML: Chronic Phase	CML: Accelerated Phase	CML: Blast Phase
Number of Participants Analyzed [units: participants]	**31**	**8**	**2**
Kaplan-Meier Estimates for Duration of Best Hematologic Response [units: months] Median (Full Range)	**7.01 (1.41 to 59.51)**	**5.47 (2.40 to 19.70)**	**2.67 (1.74 to 3.59)**

No statistical analysis provided for Kaplan-Meier Estimates for Duration of Best Hematologic Response

15. Secondary: Kaplan-Meier Estimates for Duration of Best Cytogenetic Response [Time Frame: up to four years]

Measure Type	Secondary
Measure Title	Kaplan-Meier Estimates for Duration of Best Cytogenetic Response
Measure Description	Duration of response is defined as the time from first reported date of cytogenetic response until the earliest date of objective evidence of disease progression, relapse or death. Data was censored at the last examination date for participants with ongoing response or participants who discontinued treatment for reasons other than adverse event, disease progression or death.
Time Frame	up to four years
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.
Intent to treat population of participants who had a response

Reporting Groups

	Description
CML: Chronic Phase	Study participants with chronic myeloid leukemia (CML) in the chronic phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance

	therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Accelerated Phase	Study participants with chronic myeloid leukemia (CML) in the accelerated phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Blast Phase	Study participants with chronic myeloid leukemia (CML) in the blast phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.

Measured Values

	CML: Chronic Phase	CML: Accelerated Phase	CML: Blast Phase
Number of Participants Analyzed [units: participants]	**10**	**1**	**0**
Kaplan-Meier Estimates for Duration of Best Cytogenetic Response [units: months] Median (Full Range)	**6.01 (0.92 to 51.94)**	**0.07 (0.07 to 0.07)**	

No statistical analysis provided for Kaplan-Meier Estimates for Duration of Best Cytogenetic Response

16. Secondary: Kaplan-Meier Estimates for Time to Disease Progression [Time Frame: up to 4 years]

Measure Type	Secondary
Measure Title	Kaplan-Meier Estimates for Time to Disease Progression
Measure Description	Time to disease progression is defined as the time from the initiation of treatment until the onset date of death, the development of CML accelerated phase or blast phase, or the loss of complete hematologic response or major cytogenetic response, whichever came first. Participants were censored only if they did not have progression or if they discontinued treatment for reasons other than AE, progression or death.
Time Frame	up to 4 years
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.
Intent to treat

Reporting Groups

	Description
CML: Chronic Phase	Study participants with chronic myeloid leukemia (CML) in the chronic phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Accelerated Phase	Study participants with chronic myeloid leukemia (CML) in the accelerated phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.

CML: Blast Phase	Study participants with chronic myeloid leukemia (CML) in the blast phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
Total Participants	Treatment included induction therapy of subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.

Measured Values

	CML: Chronic Phase	CML: Accelerated Phase	CML: Blast Phase	Total Participants
Number of Participants Analyzed [units: participants]	**46**	**31**	**23**	**100**
Kaplan-Meier Estimates for Time to Disease Progression [units: months] Median (95% Confidence Interval)	**7.50 (5.86 to 9.64)**	**4.84 (3.55 to 6.81)**	**2.04 (1.35 to 2.73)**	**4.38 (3.55 to 6.45)**

No statistical analysis provided for Kaplan-Meier Estimates for Time to Disease Progression

17. Secondary: Kaplan-Meier Estimates for Overall Survival [Time Frame: up to 4 years]

Measure Type	Secondary
Measure Title	Kaplan-Meier Estimates for Overall Survival
Measure Description	Overall survival is defined as the time from the initiation of treatment until death from any cause or the last day of participant contact or evaluation for participants that were lost to follow-up. Participants were censored t the last recorded contract or evaluation when a participant was alive at time of analysis. A quarterly phone survey was conducted to collect survival data for participants who discontinued from the study.
Time Frame	up to 4 years
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.
Intent to treat

Reporting Groups

	Description
CML: Chronic Phase	Study participants with chronic myeloid leukemia (CML) in the chronic phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Accelerated Phase	Study participants with chronic myeloid leukemia (CML) in the accelerated phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
CML: Blast Phase	Study participants with chronic myeloid leukemia (CML) in the blast phase at the time of enrollment. Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy

	was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.
Total Participants	Treatment included induction therapy of subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.

Measured Values

	CML: Chronic Phase	CML: Accelerated Phase	CML: Blast Phase	Total Participants
Number of Participants Analyzed [units: participants]	**46**	**31**	**23**	**100**
Kaplan-Meier Estimates for Overall Survival [units: months] Median (95% Confidence Interval)	**33.91 (23.75 to NA)** [1]	**17.27 (10.56 to 28.45)**	**3.52 (2.57 to 5.16)**	**17.27 (14.24 to 28.03)**

[1] A large percentage of participants were censored

No statistical analysis provided for Kaplan-Meier Estimates for Overall Survival

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	up to 4 years
Additional Description	No text entered.

Reporting Groups

	Description
Omacetaxine	Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.

Serious Adverse Events

	Omacetaxine
Total, serious adverse events	
# participants affected / at risk	**63/100 (63.00%)**
Blood and lymphatic system disorders	
Anaemia *1	
# participants affected / at risk	**3/100 (3.00%)**
# events	**3**
Anaemia haemolytic autoimmune *1	
# participants affected / at risk	**1/100 (1.00%)**
# events	**1**
Bone marrow failure *1	
# participants affected / at risk	**5/100 (5.00%)**
# events	**6**
Febrile bone marrow aplasia *1	
# participants affected / at risk	**2/100 (2.00%)**
# events	**2**

Febrile neutropenia [*1]	
# participants affected / at risk	**9/100 (9.00%)**
# events	**14**
Leukocytosis [*1]	
# participants affected / at risk	**1/100 (1.00%)**
# events	**1**
Neutropenia [*1]	
# participants affected / at risk	**1/100 (1.00%)**
# events	**1**
Pancytopenia [*1]	
# participants affected / at risk	**2/100 (2.00%)**
# events	**2**
Thrombocytopenia [*1]	
# participants affected / at risk	**6/100 (6.00%)**
# events	**10**
Cardiac disorders	
Acute coronary syndrome [*1]	
# participants affected / at risk	**1/100 (1.00%)**
# events	**1**
Atrial fibrillation [*1]	
# participants affected / at risk	**1/100 (1.00%)**
# events	**1**
Cardiac failure congestive [*1]	
# participants affected / at risk	**1/100 (1.00%)**
# events	**1**
Pericardial effusion [*1]	
# participants affected / at risk	**1/100 (1.00%)**
# events	**1**
Pericarditis [*1]	
# participants affected / at risk	**1/100 (1.00%)**
# events	**1**
Tachycardia [*1]	
# participants affected / at risk	**1/100 (1.00%)**
# events	**1**
Ear and labyrinth disorders	
Vertigo [*1]	
# participants affected / at risk	**1/100 (1.00%)**
# events	**1**
Gastrointestinal disorders	
Diarrhoea [*1]	
# participants affected / at risk	**4/100 (4.00%)**
# events	**4**
Gastrointestinal haemorrhage [*1]	
# participants affected / at risk	**2/100 (2.00%)**
# events	**2**
Pancreatitis [*1]	
# participants affected / at risk	**1/100 (1.00%)**
# events	**1**

Stomatitis [*1]	
# participants affected / at risk	2/100 (2.00%)
# events	2
General disorders	
Chest pain [*1]	
# participants affected / at risk	1/100 (1.00%)
# events	1
Death [*1]	
# participants affected / at risk	1/100 (1.00%)
# events	1
Disease progression [*1]	
# participants affected / at risk	8/100 (8.00%)
# events	8
Fatigue [*1]	
# participants affected / at risk	2/100 (2.00%)
# events	2
Localised oedema [*1]	
# participants affected / at risk	1/100 (1.00%)
# events	1
Multi-organ failure [*1]	
# participants affected / at risk	1/100 (1.00%)
# events	1
Pyrexia [*1]	
# participants affected / at risk	4/100 (4.00%)
# events	5
Hepatobiliary disorders	
Cholelithiasis [*1]	
# participants affected / at risk	1/100 (1.00%)
# events	1
Infections and infestations	
Bacteraemia [*1]	
# participants affected / at risk	1/100 (1.00%)
# events	4
Catheter sepsis [*1]	
# participants affected / at risk	2/100 (2.00%)
# events	2
Injection site infection [*1]	
# participants affected / at risk	1/100 (1.00%)
# events	1
Lung infection [*1]	
# participants affected / at risk	2/100 (2.00%)
# events	2
Pneumonia [*1]	
# participants affected / at risk	5/100 (5.00%)
# events	5
Sepsis [*1]	
# participants affected / at risk	3/100 (3.00%)
# events	4

Tonsillitis [*1]	
# participants affected / at risk	1/100 (1.00%)
# events	2
Viral infection [*1]	
# participants affected / at risk	1/100 (1.00%)
# events	1
Injury, poisoning and procedural complications	
Post procedural haemorrhage [*1]	
# participants affected / at risk	1/100 (1.00%)
# events	1
Subdural haematoma [*1]	
# participants affected / at risk	1/100 (1.00%)
# events	1
Transfusion reaction [*1]	
# participants affected / at risk	1/100 (1.00%)
# events	2
Metabolism and nutrition disorders	
Dehydration [*1]	
# participants affected / at risk	1/100 (1.00%)
# events	1
Failure to thrive [*1]	
# participants affected / at risk	2/100 (2.00%)
# events	2
Hypercalcaemia [*1]	
# participants affected / at risk	3/100 (3.00%)
# events	3
Musculoskeletal and connective tissue disorders	
Back pain [*1]	
# participants affected / at risk	1/100 (1.00%)
# events	1
Neck pain [*1]	
# participants affected / at risk	1/100 (1.00%)
# events	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
Blast cell crisis [*1]	
# participants affected / at risk	1/100 (1.00%)
# events	1
Chronic myeloid leukaemia [*1]	
# participants affected / at risk	2/100 (2.00%)
# events	2
Leukaemia [*1]	
# participants affected / at risk	2/100 (2.00%)
# events	2
Metastatic neoplasm [*1]	
# participants affected / at risk	1/100 (1.00%)
# events	1
Myelodysplastic syndrome [*1]	
# participants affected / at risk	1/100 (1.00%)

# events	1
Nervous system disorders	
Cerebral haemorrhage *1	
# participants affected / at risk	3/100 (3.00%)
# events	3
Cerebral ischaemia *1	
# participants affected / at risk	1/100 (1.00%)
# events	1
Convulsion *1	
# participants affected / at risk	1/100 (1.00%)
# events	1
Psychiatric disorders	
Mood altered *1	
# participants affected / at risk	1/100 (1.00%)
# events	1
Respiratory, thoracic and mediastinal disorders	
Acute pulmonary oedema *1	
# participants affected / at risk	1/100 (1.00%)
# events	1
Dyspnoea *1	
# participants affected / at risk	1/100 (1.00%)
# events	1
Pulmonary embolism *1	
# participants affected / at risk	1/100 (1.00%)
# events	1
Pulmonary haemorrhage *1	
# participants affected / at risk	1/100 (1.00%)
# events	1
Vascular disorders	
Hypotension *1	
# participants affected / at risk	1/100 (1.00%)
# events	1

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA (10.0)

Other Adverse Events

Hide Other Adverse Events

Time Frame	up to 4 years
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Omacetaxine	Treatment was the same for all cohorts: induction therapy was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 14 consecutive days every 28 (±3) days for up to 6 cycles. Maintenance therapy

was subcutaneous (SC) administration of omacetaxine at 1.25 mg/m^2 twice a day (BID), administered for 7 consecutive days every 28 (±3) days for up to 24 months.

Other Adverse Events

	Omacetaxine
Total, other (not including serious) adverse events	
# participants affected / at risk	**99/100 (99.00%)**
Blood and lymphatic system disorders	
Anaemia [*1]	
# participants affected / at risk	**51/100 (51.00%)**
# events	**132**
Bone marrow failure [*1]	
# participants affected / at risk	**6/100 (6.00%)**
# events	**7**
Febrile neutropenia [*1]	
# participants affected / at risk	**17/100 (17.00%)**
# events	**24**
Leukocytosis [*1]	
# participants affected / at risk	**7/100 (7.00%)**
# events	**10**
Leukopenia [*1]	
# participants affected / at risk	**13/100 (13.00%)**
# events	**55**
Lymphopenia [*1]	
# participants affected / at risk	**8/100 (8.00%)**
# events	**20**
Neutropenia [*1]	
# participants affected / at risk	**31/100 (31.00%)**
# events	**114**
Thrombocytopenia [*1]	
# participants affected / at risk	**62/100 (62.00%)**
# events	**192**
Cardiac disorders	
Tachycardia [*1]	
# participants affected / at risk	**5/100 (5.00%)**
# events	**6**
Gastrointestinal disorders	
Abdominal distension [*1]	
# participants affected / at risk	**5/100 (5.00%)**
# events	**5**
Abdominal pain [*1]	
# participants affected / at risk	**15/100 (15.00%)**
# events	**21**
Abdominal pain upper [*1]	
# participants affected / at risk	**7/100 (7.00%)**
# events	**7**
Constipation [*1]	
# participants affected / at risk	**11/100 (11.00%)**
# events	**12**

Diarrhoea [*1]	
# participants affected / at risk	42/100 (42.00%)
# events	71
Dyspepsia [*1]	
# participants affected / at risk	7/100 (7.00%)
# events	7
Gingival bleeding [*1]	
# participants affected / at risk	5/100 (5.00%)
# events	5
Nausea [*1]	
# participants affected / at risk	29/100 (29.00%)
# events	44
Stomatitis [*1]	
# participants affected / at risk	10/100 (10.00%)
# events	16
Vomiting [*1]	
# participants affected / at risk	17/100 (17.00%)
# events	22
General disorders	
Asthenia [*1]	
# participants affected / at risk	19/100 (19.00%)
# events	46
Chills [*1]	
# participants affected / at risk	10/100 (10.00%)
# events	13
Disease progression [*1]	
# participants affected / at risk	10/100 (10.00%)
# events	11
Fatigue [*1]	
# participants affected / at risk	24/100 (24.00%)
# events	37
Injection site erythema [*1]	
# participants affected / at risk	11/100 (11.00%)
# events	34
Injection site rash [*1]	
# participants affected / at risk	5/100 (5.00%)
# events	5
Injection site reaction [*1]	
# participants affected / at risk	5/100 (5.00%)
# events	6
Mucosal inflammation [*1]	
# participants affected / at risk	5/100 (5.00%)
# events	5
Oedema peripheral [*1]	
# participants affected / at risk	14/100 (14.00%)
# events	22
Pyrexia [*1]	
# participants affected / at risk	28/100 (28.00%)
# events	50

Infections and infestations	
Bronchitis [*1]	
# participants affected / at risk	**8/100 (8.00%)**
# events	**8**
Cellulitis [*1]	
# participants affected / at risk	**6/100 (6.00%)**
# events	**8**
Pneumonia [*1]	
# participants affected / at risk	**13/100 (13.00%)**
# events	**15**
Upper respiratory tract infection [*1]	
# participants affected / at risk	**9/100 (9.00%)**
# events	**13**
Urinary tract infection [*1]	
# participants affected / at risk	**6/100 (6.00%)**
# events	**7**
Injury, poisoning and procedural complications	
Contusion [*1]	
# participants affected / at risk	**8/100 (8.00%)**
# events	**9**
Investigations	
Alanine aminotransferase increased [*1]	
# participants affected / at risk	**6/100 (6.00%)**
# events	**6**
Metabolism and nutrition disorders	
Anorexia [*1]	
# participants affected / at risk	**14/100 (14.00%)**
# events	**15**
Hyperuricaemia [*1]	
# participants affected / at risk	**8/100 (8.00%)**
# events	**9**
Hypokalaemia [*1]	
# participants affected / at risk	**8/100 (8.00%)**
# events	**10**
Musculoskeletal and connective tissue disorders	
Arthralgia [*1]	
# participants affected / at risk	**10/100 (10.00%)**
# events	**11**
Back pain [*1]	
# participants affected / at risk	**7/100 (7.00%)**
# events	**7**
Bone pain [*1]	
# participants affected / at risk	**9/100 (9.00%)**
# events	**10**
Pain in extremity [*1]	
# participants affected / at risk	**15/100 (15.00%)**
# events	**18**
Nervous system disorders	

Dizziness *1	
# participants affected / at risk	**6/100 (6.00%)**
# events	**8**
Headache *1	
# participants affected / at risk	**20/100 (20.00%)**
# events	**27**
Psychiatric disorders	
Insomnia *1	
# participants affected / at risk	**7/100 (7.00%)**
# events	**9**
Respiratory, thoracic and mediastinal disorders	
Cough *1	
# participants affected / at risk	**13/100 (13.00%)**
# events	**22**
Dyspnoea *1	
# participants affected / at risk	**8/100 (8.00%)**
# events	**10**
Epistaxis *1	
# participants affected / at risk	**17/100 (17.00%)**
# events	**19**
Pharyngolaryngeal pain *1	
# participants affected / at risk	**9/100 (9.00%)**
# events	**9**
Skin and subcutaneous tissue disorders	
Alopecia *1	
# participants affected / at risk	**7/100 (7.00%)**
# events	**7**
Rash *1	
# participants affected / at risk	**7/100 (7.00%)**
# events	**8**
Vascular disorders	
Haematoma *1	
# participants affected / at risk	**5/100 (5.00%)**
# events	**12**
Hypertension *1	
# participants affected / at risk	**6/100 (6.00%)**
# events	**8**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA (10.0)

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:** Sponsor has the right 60 days before submission for publication to review/provide comments. If the Sponsor's review shows that potentially patentable subject matter would be disclosed, publication or public disclosure shall be delayed for up to 90 additional days in order for the Sponsor, or Sponsor's designees, to file the necessary patent applications. In multicenter trials, each PI will postpone single center publications until after disclosure or publication of multicenter data.

Results Point of Contact:

Name/Title: Director, Clinical Research
Organization: Teva Branded Pharmaceutical Products, R&D Inc.
phone: 215-591-3000
e-mail: ustevatrials@tevapharm.com

No publications provided by Teva Pharmaceutical Industries

Publications automatically indexed to this study:

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Responsible Party:	Teva Pharmaceutical Industries (Teva Branded Pharmaceutical Products, R&D Inc.)
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