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Trial record **2 of 2** for: CSTI571K2301

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Efficacy of 400 Mg Versus 800 Mg Imatinib in Chronic Myeloid Leukemia in Chronic Phase Patients - TOPS (Tyrosine Kinase Inhibitor Optimization and Selectivity) (TOPS)

This study has been terminated.

(This study was prematurely discontinued because no improvement was observed in the 800mg dose compared to 400mg dose)

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT00124748

First received: July 27, 2005
Last updated: January 5, 2012
Last verified: January 2012
History of Changes

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Results First Received: November 2, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Leukemia, Myeloid, Chronic Phase
Intervention:	Drug: Imatinib mesylate

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
Imatinib 400 mg	Oral dose of 400mg Imatinib once daily (q.d.). All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted, reduced, or escalated based on guidelines defined in protocol.
Imatinib 800 mg	Patients randomized to receive 800 mg Imatinib were to receive 400 mg twice daily (b.i.d.) oral administration, in the morning and the evening. All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted or reduced based on guidelines defined in protocol.

Participant Flow: Overall Study

	Imatinib 400 mg	Imatinib 800 mg
STARTED	**157**	**319**
Safety Population	**157**	**316**
COMPLETED	**14**	**35**
NOT COMPLETED	**143**	**284**
Adverse Event	**8**	**39**

Abnormal laboratory Value	**2**	**2**
Abnormal Procedure	**0**	**1**
Lack of Efficacy	**20**	**41**
No longer requires study drug	**1**	**1**
Protocol Violation	**3**	**1**
Withdrawal by Subject	**5**	**15**
Lost to Follow-up	**2**	**7**
Administrative Problem(Study Terminated)	**101**	**174**
Death	**1**	**3**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

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

Reporting Groups

	Description
Imatinib 400 mg	Oral dose of 400mg Imatinib once daily (q.d.). All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted, reduced, or escalated based on guidelines defined in protocol.
Imatinib 800 mg	Patients randomized to receive 800 mg Imatinib were to receive 400 mg twice daily (b.i.d.) oral administration, in the morning and the evening. All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted or reduced based on guidelines defined in protocol.
Total	Total of all reporting groups

Baseline Measures

	Imatinib 400 mg	Imatinib 800 mg	Total
Number of Participants [units: participants]	**157**	**319**	**476**
Age [units: years] Mean (Standard Deviation)	**46.2 (14.90)**	**48.2 (13.89)**	**47.6 (14.25)**
Gender [units: participants]			
Female	**73**	**136**	**209**
Male	**84**	**183**	**267**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants With Major Molecular Response (MMR) Rates at 12 Months [Time Frame: 12 months]

Measure Type	Primary
Measure Title	Percentage of Participants With Major Molecular Response (MMR) Rates at 12 Months
Measure Description	MMR is defined as Bcr-Abl (A fusion gene of the breakpoint cluster region [Bcr] gene and Abelson proto-oncogene [Abl] genes) transcript ratio ≤0.1% (≥ 3 log reduction of BCR-ABL transcripts from a standardized baseline), as detected by reverse transcriptase polymerase chain reaction [RT-PCR] (performed centrally).
Time Frame	12 months
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat (ITT) population consisted of all patients who are randomized into the study.

Reporting Groups

	Description
Imatinib 400 mg	Oral dose of 400mg Imatinib once daily (q.d.). All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted, reduced, or escalated based on guidelines defined in protocol.
Imatinib 800 mg	Patients randomized to receive 800 mg Imatinib were to receive 400 mg twice daily (b.i.d.) oral administration, in the morning and the evening. All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted or reduced based on guidelines defined in protocol.

Measured Values

	Imatinib 400 mg	**Imatinib 800 mg**
Number of Participants Analyzed [units: participants]	**157**	**319**
Percentage of Participants With Major Molecular Response (MMR) Rates at 12 Months [units: Percentage of participants]	**38.9**	**45.1**

No statistical analysis provided for Percentage of Participants With Major Molecular Response (MMR) Rates at 12 Months

2. Secondary: Percentage of Participants With Major Molecular Response (MMR) Rates at 24, 36, and 42 Months [Time Frame: 24, 36 and 42 months]

Measure Type	Secondary
Measure Title	Percentage of Participants With Major Molecular Response (MMR) Rates at 24, 36, and 42 Months
Measure Description	MMR is defined as Bcr-Abl (A fusion gene of the breakpoint cluster region [Bcr] gene and Abelson proto-oncogene [Abl] genes) transcript ratio ≤0.1% (≥ 3 log reduction of BCR-ABL transcripts from a standardized baseline), as

	detected by reverse transcriptase polymerase chain reaction [RT-PCR] (performed centrally).
Time Frame	24, 36 and 42 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 (ITT) population consisted of all patients who are randomized into the study.

Reporting Groups

	Description
Imatinib 400 mg	Oral dose of 400mg Imatinib once daily (q.d.). All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted, reduced, or escalated based on guidelines defined in protocol.
Imatinib 800 mg	Patients randomized to receive 800 mg Imatinib were to receive 400 mg twice daily (b.i.d.) oral administration, in the morning and the evening. All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted or reduced based on guidelines defined in protocol.

Measured Values

	Imatinib 400 mg	**Imatinib 800 mg**
Number of Participants Analyzed [units: participants]	**157**	**319**
Percentage of Participants With Major Molecular Response (MMR) Rates at 24, 36, and 42 Months [units: Percentage of participants]		
24 months	**53.5**	**50.8**
36 months	**52.2**	**49.8**
42 months	**51.6**	**50.2**

No statistical analysis provided for Percentage of Participants With Major Molecular Response (MMR) Rates at 24, 36, and 42 Months

3. Secondary: Percentage of Participants With Complete Cytogenetic Response (CCyR) Rate at 12, 24, 36, 42 Months [Time Frame: 12, 24, 36, 42 months]

Measure Type	Secondary
Measure Title	Percentage of Participants With Complete Cytogenetic Response (CCyR) Rate at 12, 24, 36, 42 Months
Measure Description	Cytogenetic response (CyR)is the percentage of Philadelphia chromosome positive metaphases (among at least 20 metaphase cells in bone marrow (BM)) with Complete Cytogenetic Response (CCyR) being 0 percent.
Time Frame	12, 24, 36, 42 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 (ITT) population consisted of all patients who are randomized into the study.

Reporting Groups

	Description
Imatinib 400 mg	Oral dose of 400mg Imatinib once daily (q.d.). All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted, reduced, or escalated based on guidelines defined in protocol.
Imatinib 800 mg	Patients randomized to receive 800 mg Imatinib were to receive 400 mg twice daily (b.i.d.) oral administration, in the morning and the evening. All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted or reduced based on guidelines defined in protocol.

Measured Values

	Imatinib 400 mg	**Imatinib 800 mg**

Number of Participants Analyzed [units: participants]	**157**	**319**
Percentage of Participants With Complete Cytogenetic Response (CCyR) Rate at 12, 24, 36, 42 Months [units: Percentage of Participants]		
12 months	**66.9**	**70.2**
24 months	**76.4**	**76.8**
36 months	**79.0**	**80.6**
42 months	**80.3**	**81.5**

No statistical analysis provided for Percentage of Participants With Complete Cytogenetic Response (CCyR) Rate at 12, 24, 36, 42 Months

4. Secondary: Percentage of Participants With Complete Hematological Response (CHR) Rates at 12, 24, 36, and 42 Months [Time Frame: 12, 24, 36, and 42 months]

Measure Type	Secondary
Measure Title	Percentage of Participants With Complete Hematological Response (CHR) Rates at 12, 24, 36, and 42 Months
Measure Description	Complete Hematologic Response (CHR) is where all of the following criteria must be present for ≥4 weeks: White Blood Cell (WBC) count <10 x 109/L, Platelet count <450 x 109/L, Basophils <5%, No blasts and promyelocytes in Peripheral Blood (PB), (Myelocytes + metamyelocytes) < 5% in PB and No evidence of extramedullary involvement.
Time Frame	12, 24, 36, and 42 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 (ITT) population consisted of all patients who are randomized into the study.

Reporting Groups

	Description
Imatinib 400 mg	Oral dose of 400mg Imatinib once daily (q.d.). All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted, reduced, or escalated based on guidelines defined in protocol.
Imatinib 800 mg	Patients randomized to receive 800 mg Imatinib were to receive 400 mg twice daily (b.i.d.) oral administration, in the morning and the evening. All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted or reduced based on guidelines defined in protocol.

Measured Values

	Imatinib 400 mg	Imatinib 800 mg
Number of Participants Analyzed [units: participants]	**157**	**319**
Percentage of Participants With Complete Hematological Response (CHR) Rates at 12, 24, 36, and 42 Months [units: Percentage of participants]		
12 months	**94.9**	**93.7**
24 months	**94.9**	**93.7**
36 months	**96.2**	**94.4**
42 months	**96.2**	**94.4**

No statistical analysis provided for Percentage of Participants With Complete Hematological Response (CHR) Rates at 12, 24, 36, and 42 Months

5. Secondary: Percentage of Patients With Undetectable Levels of Bcr-Abl (A Fusion Gene of the Breakpoint Cluster Region [Bcr] Gene and Abelson Proto-oncogene [Abl] Genes) Transcripts [Time Frame: 12 , 24, 36 and 42 months]

Measure Type	Secondary

Measure Title	Percentage of Patients With Undetectable Levels of Bcr-Abl (A Fusion Gene of the Breakpoint Cluster Region [Bcr] Gene and Abelson Proto-oncogene [Abl] Genes) Transcripts
Measure Description	"Undetectable levels" or Complete molecular response is defined as Bcr-Abl ratio (%) on international scale (IS) <= 0.0032% (≥ 4.5 log reduction of BCR-Abl transcripts from a standardized baseline).
Time Frame	12 , 24, 36 and 42 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 (ITT) population consisted of all patients who were randomized into the study.

Reporting Groups

	Description
Imatinib 400 mg	Oral dose of 400mg Imatinib once daily (q.d.). All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted, reduced, or escalated based on guidelines defined in protocol.
Imatinib 800 mg	Patients randomized to receive 800 mg Imatinib were to receive 400 mg twice daily (b.i.d.) oral administration, in the morning and the evening. All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted or reduced based on guidelines defined in protocol.

Measured Values

	Imatinib 400 mg	**Imatinib 800 mg**
Number of Participants Analyzed [units: participants]	**157**	**319**
Percentage of Patients With Undetectable Levels of Bcr-Abl (A Fusion Gene of the Breakpoint Cluster Region [Bcr] Gene and Abelson Proto-oncogene [Abl] Genes) Transcripts [units: Percentage of Partcipants]		

12 Months	**4.5**	**4.7**
24 Months	**11.5**	**10.3**
36 Months	**12.7**	**13.2**
42 Months	**14.6**	**12.5**

No statistical analysis provided for Percentage of Patients With Undetectable Levels of Bcr-Abl (A Fusion Gene of the Breakpoint Cluster Region [Bcr] Gene and Abelson Proto-oncogene [Abl] Genes) Transcripts

6. Secondary: Time to First Major Molecular Response [Time Frame: 42 months overall]

Measure Type	Secondary
Measure Title	Time to First Major Molecular Response
Measure Description	MMR is defined as Bcr-Abl (A fusion gene of the breakpoint cluster region [Bcr] gene and Abelson proto-oncogene [Abl] genes) transcript ratio ≤0.1% (≥ 3 log reduction of BCR-ABL transcripts from a standardized baseline), as detected by reverse transcriptase polymerase chain reaction [RT-PCR] (performed centrally). Time to MMR (months) = (date of first MMR or censoring - date of randomization + 1) / 30.4375. Time to first MMR was evaluated using the Kaplan-Meier method
Time Frame	42 months overall
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 (ITT) population consisted of all patients who were randomized to the study treatment.

Reporting Groups

	Description

Imatinib 400 mg	Oral dose of 400mg Imatinib once daily (q.d.). All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted, reduced, or escalated based on guidelines defined in protocol.
Imatinib 800 mg	Patients randomized to receive 800 mg Imatinib were to receive 400 mg twice daily (b.i.d.) oral administration, in the morning and the evening. All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted or reduced based on guidelines defined in protocol.

Measured Values

	Imatinib 400 mg	Imatinib 800 mg
Number of Participants Analyzed [units: participants]	**157**	**319**
Time to First Major Molecular Response [units: Months] Median (95% Confidence Interval)	**13.6 (10.8 to 15.6)**	**8.4 (8.3 to 9.0)**

No statistical analysis provided for Time to First Major Molecular Response

7. Secondary: Time to First Complete Cytogenetic Response [Time Frame: 60 months overall]

Measure Type	Secondary
Measure Title	Time to First Complete Cytogenetic Response
Measure Description	Cytogenetic response (CyR) is the percentage of Philadelphia positive metaphases (among at least 20 metaphase cells in Bone Marrow) with Complete Cytogenetic Response (CCyR) being 0 percent. Time to CCyR (months) = (date of first CCyR or censoring - date of randomization + 1) / 30.4375. Time to first CCyR was evaluated using the Kaplan-Meier method.
Time Frame	60 months overall
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 (ITT) population consisted of all patients who are randomized into the study.

Reporting Groups

	Description
Imatinib 400 mg	Oral dose of 400mg Imatinib once daily (q.d.). All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted, reduced, or escalated based on guidelines defined in protocol.
Imatinib 800 mg	Patients randomized to receive 800 mg Imatinib were to receive 400 mg twice daily (b.i.d.) oral administration, in the morning and the evening. All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted or reduced based on guidelines defined in protocol.

Measured Values

	Imatinib 400 mg	**Imatinib 800 mg**
Number of Participants Analyzed [units: participants]	**157**	**319**
Time to First Complete Cytogenetic Response [units: Months] Median (95% Confidence Interval)	**10.8 (5.9 to 11.2)**	**5.8 (5.8 to 6.0)**

No statistical analysis provided for Time to First Complete Cytogenetic Response

8. Secondary: Time to First Complete Hematological Response (CHR)] [Time Frame: 60 months overall]

Measure Type	Secondary
Measure Title	Time to First Complete Hematological Response (CHR)]
Measure Description	Complete Hematological Response (CHR) is defined is where all of the following criteria must be present for ≥4 weeks: White Blood Cell (WBC) count <10 x 109/L, Platelet count <450 x 109/L, Basophils <5%, No blasts and promyelocytes

	in Peripheral Blood (PB), (Myelocytes + metamyelocytes) < 5% in PB and No evidence of extramedullary involvement. Time to CHR (months) = (date of first CHR or censoring - date of randomization + 1) / 30.4375. Time to first CHR was evaluated using the Kaplan-Meier method.
Time Frame	60 months overall
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 (ITT) population consisted of all patients who are randomized into the study.

Reporting Groups

	Description
Imatinib 400 mg	Oral dose of 400mg Imatinib once daily (q.d.). All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted, reduced, or escalated based on guidelines defined in protocol.
Imatinib 800 mg	Patients randomized to receive 800 mg Imatinib were to receive 400 mg twice daily (b.i.d.) oral administration, in the morning and the evening. All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted or reduced based on guidelines defined in protocol.

Measured Values

	Imatinib 400 mg	**Imatinib 800 mg**
Number of Participants Analyzed [units: participants]	**157**	**319**
Time to First Complete Hematological Response (CHR)] [units: Months] Median (95% Confidence Interval)	**1.0 (1.0 to 1.0)**	**1.0 (1.0 to 1.0)**

No statistical analysis provided for Time to First Complete Hematological Response (CHR)]

9. Secondary: Estimated Rate of Event Free Survival (EFS) in Two Treatment Arms [Time Frame: 60 months over all]

Measure Type	Secondary
Measure Title	Estimated Rate of Event Free Survival (EFS) in Two Treatment Arms
Measure Description	EFS on treatment was defined as time between randomization and either (1) death due to any cause during study treatment, (2) progression to accelerated phase (AP) or blast crisis (BC) on treatment, (3) loss of complete hematological response (CHR), or (4) loss of major cytogenic response (MCyR) while on treatment. Estimated rate of EFS was analyzed by Kaplan-Meier estimate (percent probability and 95% Confidence interval).
Time Frame	60 months over all
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 (ITT) population consisted of all patients who are randomized into the study.

Reporting Groups

	Description
Imatinib 400 mg	Oral dose of 400mg Imatinib once daily (q.d.). All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted, reduced, or escalated based on guidelines defined in protocol.
Imatinib 800 mg	Patients randomized to receive 800 mg Imatinib were to receive 400 mg twice daily (b.i.d.) oral administration, in the morning and the evening. All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted or reduced based on guidelines defined in protocol.

Measured Values

	Imatinib 400 mg	**Imatinib 800 mg**
Number of Participants Analyzed [units: participants]	**157**	**319**

Estimated Rate of Event Free Survival (EFS) in Two Treatment Arms [units: Percent probability] Number (95% Confidence Interval)		
12 Months	**95.3 (90.5 to 97.7)**	**98.0 (95.6 to 99.1)**
24 Months	**94.6 (89.5 to 97.3)**	**95.3 (92.1 to 97.3)**
36 Months	**92.3 (86.5 to 95.7)**	**94.5 (91.1 to 96.7)**
42 Months	**92.3 (86.5 to 95.7)**	**94.1 (90.5 to 96.3)**
48 Months	**92.3 (86.5 to 95.7)**	**93.6 (89.9 to 96.0)**
60 Months	**90.3 (82.7 to 94.7)**	**93.6 (89.9 to 96.0)**

No statistical analysis provided for Estimated Rate of Event Free Survival (EFS) in Two Treatment Arms

10. Secondary: Estimated Rate of Progression Free Survival (PFS) in Two Treatment Arms [Time Frame: 60 months over all and follow up period]

Measure Type	Secondary
Measure Title	Estimated Rate of Progression Free Survival (PFS) in Two Treatment Arms
Measure Description	PFS on study which was defined as time between randomization and either (1) death due to any cause on treatment of during follow-up after discontinuation of treatment or (2) progression to accelerated phase (AP) or blast crisis (BC) on treatment during follow-up after discontinuation of study treatment. Estimated rate of PFS was analyzed by Kaplan-Meier estimate (percent probability and 95% Confidence interval).
Time Frame	60 months over all and follow up period

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 (ITT) population consisted of all patients who are randomized into the study.

Reporting Groups

	Description
Imatinib 400 mg	Oral dose of 400mg Imatinib once daily (q.d.). All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted, reduced, or escalated based on guidelines defined in protocol.
Imatinib 800 mg	Patients randomized to receive 800 mg Imatinib were to receive 400 mg twice daily (b.i.d.) oral administration, in the morning and the evening. All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted or reduced based on guidelines defined in protocol.

Measured Values

	Imatinib 400 mg	Imatinib 800 mg
Number of Participants Analyzed [units: participants]	**157**	**319**
Estimated Rate of Progression Free Survival (PFS) in Two Treatment Arms [units: Percent probability] Number (95% Confidence Interval)		
12 Months	**97.4 (93.2 to 99.0)**	**98.7 (96.5 to 99.5)**
24 Months	**95.9 (91.2 to 98.2)**	**97.5 (94.9 to 98.8)**
36 Months	**94.4 (89.0 to 97.1)**	**96.7 (93.7 to 98.3)**
	94.4	**96.3**

42 Months	**(89.0 to 97.1)**	**(93.2 to 98.0)**
48 Months	**94.4 (89.0 to 97.1)**	**95.8 (92.5 to 97.7)**
60 Months	**94.4 (89.0 to 97.1)**	**95.8 (92.5 to 97.7)**

No statistical analysis provided for Estimated Rate of Progression Free Survival (PFS) in Two Treatment Arms

11. Secondary: Estimated Rate of Progression to Accelerated Phase (AC)/Blast Crisis (BC) in Two Treatment Arms [Time Frame: 60 months over all and follow up period]

Measure Type	Secondary
Measure Title	Estimated Rate of Progression to Accelerated Phase (AC)/Blast Crisis (BC) in Two Treatment Arms
Measure Description	(Accelerated Phase/Blast Crisis) AP/BC was defined as time between randomization and either (1) (Chronic Myeloid Leukemia) CML-related death (if death was primary reason for discontinuation) or (2) progression to AP or BC (during treatment). Estimated rate of AC/BC was analyzed by Kaplan-Meier estimate (percent probability and 95% Confidence interval).
Time Frame	60 months over all and follow up period
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 (ITT) population consisted of all patients who are randomized into the study.

Reporting Groups

	Description

Imatinib 400 mg	Oral dose of 400mg Imatinib once daily (q.d.). All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted, reduced, or escalated based on guidelines defined in protocol.
Imatinib 800 mg	Patients randomized to receive 800 mg Imatinib were to receive 400 mg twice daily (b.i.d.) oral administration, in the morning and the evening. All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted or reduced based on guidelines defined in protocol.

Measured Values

	Imatinib 400 mg	**Imatinib 800 mg**
Number of Participants Analyzed [units: participants]	**157**	**319**
Estimated Rate of Progression to Accelerated Phase (AC)/Blast Crisis (BC) in Two Treatment Arms [units: Percent probability] Number (95% Confidence Interval)		
12 Months	**97.4 (93.2 to 99.0)**	**99.0 (97.0 to 99.7)**
24 Months	**95.9 (91.2 to 98.2)**	**97.9 (95.3 to 99.0)**
36 Months	**95.2 (90.1 to 97.7)**	**97.5 (94.7 to 98.8)**
42 Months	**95.2 (90.1 to 97.7)**	**97.0 (94.1 to 98.5)**
48 Months	**95.2 (90.1 to 97.7)**	**97.0 (94.1 to 98.5)**
60 Months	**95.2 (90.1 to 97.7)**	**97.0 (94.1 to 98.5)**

No statistical analysis provided for Estimated Rate of Progression to Accelerated Phase (AC)/Blast Crisis (BC) in Two Treatment Arms

12. Secondary: Estimated Rate of Overall Survival (OS) in Two Treatment Arms [Time Frame: 60 months over all and follow up period]

Measure Type	Secondary
Measure Title	Estimated Rate of Overall Survival (OS) in Two Treatment Arms
Measure Description	OS was defined as time between randomization and death due to any cause during study treatment or during follow-up after discontinuation of treatment. Estimated rate of OS was analyzed by Kaplan-Meier estimate (percent probability and 95% Confidence interval).
Time Frame	60 months over all and follow up period
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 (ITT) population consisted of all patients who are randomized into the study.

Reporting Groups

	Description
Imatinib 400 mg	Oral dose of 400mg Imatinib once daily (q.d.). All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted, reduced, or escalated based on guidelines defined in protocol.
Imatinib 800 mg	Patients randomized to receive 800 mg Imatinib were to receive 400 mg twice daily (b.i.d.) oral administration, in the morning and the evening. All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted or reduced based on guidelines defined in protocol.

Measured Values

	Imatinib 400 mg	**Imatinib 800 mg**
Number of Participants Analyzed [units: participants]	**157**	**319**
Estimated Rate of Overall Survival (OS) in Two Treatment Arms [units: Percent probability]		

Number (95% Confidence Interval)		
12 Months	98.7 (94.9 to 99.7)	99.0 (97.1 to 99.7)
24 Months	97.4 (93.2 to 99.0)	97.8 (95.4 to 98.9)
36 Months	96.1 (91.4 to 98.2)	95.5 (92.5 to 97.3)
42 Months	94.7 (89.7 to 97.2)	94.8 (91.6 to 96.8)
48 Months	94.0 (88.7 to 96.8)	93.4 (89.7 to 95.8)
60 Months	94.0 (88.7 to 96.8)	93.4 (89.7 to 95.8)

No statistical analysis provided for Estimated Rate of Overall Survival (OS) in Two Treatment Arms

13. Secondary: Kaplan-Meier Estimates of Duration of First Major Molecular Response Until Confirmed Loss [Time Frame: From First major molecular response to first confirmed loss or censoring]

Measure Type	Secondary
Measure Title	Kaplan-Meier Estimates of Duration of First Major Molecular Response Until Confirmed Loss
Measure Description	Duration of MMR (months) = (date of first confirmed loss or censoring - date of MMR + 1) / 30.4375. Estimated rate of duration of first MMR was analyzed by Kaplan-Meier estimate (percent probability and 95% Confidence interval).
Time Frame	From First major molecular response to first confirmed loss or censoring
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 (ITT) population consisted of all patients who are randomized into the study.

Reporting Groups

	Description
Imatinib 400 mg	Oral dose of 400mg Imatinib once daily (q.d.). All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted, reduced, or escalated based on guidelines defined in protocol.
Imatinib 800 mg	Patients randomized to receive 800 mg Imatinib were to receive 400 mg twice daily (b.i.d.) oral administration, in the morning and the evening. All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted or reduced based on guidelines defined in protocol.

Measured Values

	Imatinib 400 mg	**Imatinib 800 mg**
Number of Participants Analyzed [units: participants]	**157**	**319**
Kaplan-Meier Estimates of Duration of First Major Molecular Response Until Confirmed Loss [units: Percent probability] Number (95% Confidence Interval)		
3 Months	**100 (100 to 100)**	**96.3 (92.9 to 98.0)**
6 Months	**98.3 (93.3 to 99.6)**	**90.7 (86.2 to 93.8)**
9 Months	**97.4 (92.2 to 99.2)**	**90.2 (85.7 to 93.4)**
12 Months	**95.6 (89.8 to 98.2)**	**88.4 (83.6 to 91.9)**
15 Months	**93.8 (87.4 to 97.0)**	**87.5 (82.5 to 91.2)**

18 Months	**92.8 (86.2 to 96.4)**	**86.1 (80.9 to 90.0)**
21 Months	**90.9 (83.8 to 95.0)**	**85.1 (79.8 to 89.1)**
24 Months	**89.9 (82.5 to 94.3)**	**83.6 (78.0 to 87.8)**
30 Months	**88.5 (80.5 to 93.4)**	**82.5 (76.8 to 86.9)**
36 Months	**85.1 (75.6 to 91.1)**	**81.1 (75.1 to 85.8)**
42 Months	**85.1 (75.6 to 91.1)**	**77.9 (70.4 to 83.8)**

No statistical analysis provided for Kaplan-Meier Estimates of Duration of First Major Molecular Response Until Confirmed Loss

14. Secondary: Kaplan-Meier Estimates of Duration of First Complete Cytogenetic Response (CCyR) [Time Frame: From first complete cytogenetic response to first confirmed loss or censoring]

Measure Type	Secondary
Measure Title	Kaplan-Meier Estimates of Duration of First Complete Cytogenetic Response (CCyR)
Measure Description	Duration of CCyR was defined as the time between date of CCyR and the earliest of either (1) loss of CCyR OR (2) (Chronic Myeloid Leukemia) CML-related death or progression to (Accelerated Phase/Blast Crisis) AP/BC during study treatment. Estimated rate of duration of first CCyR was analyzed by Kaplan-Meier estimate (percent probability and 95% Confidence interval).
Time Frame	From first complete cytogenetic response to first confirmed loss or censoring
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 (ITT) population consisted of all patients who are randomized into the study.

Reporting Groups

	Description
Imatinib 400 mg	Oral dose of 400mg Imatinib once daily (q.d.). All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted, reduced, or escalated based on guidelines defined in protocol.
Imatinib 800 mg	Patients randomized to receive 800 mg Imatinib were to receive 400 mg twice daily (b.i.d.) oral administration, in the morning and the evening. All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted or reduced based on guidelines defined in protocol.

Measured Values

	Imatinib 400 mg	**Imatinib 800 mg**
Number of Participants Analyzed [units: participants]	**157**	**319**
Kaplan-Meier Estimates of Duration of First Complete Cytogenetic Response (CCyR) [units: Percent probability] Number (95% Confidence Interval)		
6 Months	**99.1 (94.0 to 99.9)**	**99.2 (96.7 to 99.8)**
12 Months	**98.2 (93.1 to 99.6)**	**97.8 (94.7 to 99.1)**
18 Months	**98.2 (93.1 to 99.6)**	**97.3 (94.1 to 98.8)**
24 Months	**98.2 (93.1 to 99.6)**	**96.8 (93.3 to 98.4)**
30 Months	**98.2 (93.1 to 99.6)**	**96.8 (93.3 to 98.4)**

36 Months	**98.2 (93.1 to 99.6)**	**95.9 (91.9 to 98.0)**
42 Months	**98.2 (93.1 to 99.6)**	**95.9 (91.9 to 98.0)**

No statistical analysis provided for Kaplan-Meier Estimates of Duration of First Complete Cytogenetic Response (CCyR)

15. Secondary: Mean Actual Dose Intensity Per Day [Time Frame: start of treatment to Month 36]

Measure Type	Secondary
Measure Title	Mean Actual Dose Intensity Per Day
Measure Description	The mean actual dose intensity per day from start of treatment up to last dose or discontinuation was evaluated up to Month 36. Actual dose intensity (mg/day) = total dose/time on treatment (periods of zero dose are included)
Time Frame	start of treatment to Month 36
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.
Safety analysis population (SAP): consisted of all patients who received at least one dose of study medication.Subjects are summarized according to the safety treatment allocation (the dose they actually received).

Reporting Groups

	Description
Imatinib 400 mg	Oral dose of 400mg Imatinib once daily (q.d.). All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted, reduced, or escalated based on guidelines defined in protocol.
Imatinib 800 mg	Patients randomized to receive 800 mg Imatinib were to receive 400 mg twice daily (b.i.d.) oral administration, in the

	morning and the evening. All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted or reduced based on guidelines defined in protocol.

Measured Values

	Imatinib 400 mg	Imatinib 800 mg
Number of Participants Analyzed [units: participants]	**157**	**316**
Mean Actual Dose Intensity Per Day [units: mg/day] Mean (Standard Deviation)	**399.3 (83.84)**	**643.3 (158.63)**

No statistical analysis provided for Mean Actual Dose Intensity Per Day

16. Secondary: Imatinib Pharmacokinetic Trough Plasma Concentration (Cmin) at Month 12 [Time Frame: Month 12]

Measure Type	Secondary
Measure Title	Imatinib Pharmacokinetic Trough Plasma Concentration (Cmin) at Month 12
Measure Description	Imatinib PK trough plasma concentration (Cmin) was defined as any pre-dose Imatinib plasma concentration
Time Frame	Month 12
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.
Pharmakokinetic (PK) population consisted of number of patients with a pre-dose PK sample at Month 12

Reporting Groups

	Description
Imatinib 400 mg	Oral dose of 400mg Imatinib once daily (q.d.). All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted, reduced, or escalated based on guidelines defined in protocol.
Imatinib 800 mg	Patients randomized to receive 800 mg Imatinib were to receive 400 mg twice daily (b.i.d.) oral administration, in the morning and the evening. All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted or reduced based on guidelines defined in protocol.

Measured Values

	Imatinib 400 mg	Imatinib 800 mg
Number of Participants Analyzed [units: participants]	**86**	**150**
Imatinib Pharmacokinetic Trough Plasma Concentration (Cmin) at Month 12 [units: mg/mL] Mean (Standard Deviation)	**1458.2 (2259.5)**	**739.58 (1321.09)**

No statistical analysis provided for Imatinib Pharmacokinetic Trough Plasma Concentration (Cmin) at Month 12

17. Secondary: Estimated Rates of Progression Free Survival (PFS) on Treatment by Major Molecular Response (MMR) [Time Frame: 42 months]

Measure Type	Secondary
Measure Title	Estimated Rates of Progression Free Survival (PFS) on Treatment by Major Molecular Response (MMR)
Measure Description	A Landmark Kaplan-Meier analysis was performed for PFS at 42 months by MMR status at 6, 12, and 18 months to investigate their prognostic value.
Time Frame	42 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 (ITT) population consisted of all patients who were randomized to the study treatment. Patients without a valid polymerase chain reaction (PCR) assessment or those who had experienced an event before the landmark were excluded from analysis

Reporting Groups

	Description
Imatinib 400 mg	Oral dose of 400mg Imatinib once daily (q.d.). All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted, reduced, or escalated based on guidelines defined in protocol.
Imatinib 800 mg	Patients randomized to receive 800 mg Imatinib were to receive 400 mg twice daily (b.i.d.) oral administration, in the morning and the evening. All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted or reduced based on guidelines defined in protocol.

Measured Values

	Imatinib 400 mg	**Imatinib 800 mg**
Number of Participants Analyzed [units: participants]	**134**	**274**
Estimated Rates of Progression Free Survival (PFS) on Treatment by Major Molecular Response (MMR) [units: Percent probability] Number (95% Confidence Interval)		
No MMR at 6 Months	**94.8 (88.0 to 97.8)**	**95.6 (90.3 to 98.0)**
MMR at 6 Months	**100 (100 to 100)**	**99.0 (93.2 to 99.9)**
No MMR at 12 Months	**93.2 (82.9 to 97.4)**	**94.6 (87.4 to 97.7)**
MMR at 12 Months	**100 (100 to 100)**	**99.3 (95.0 to 99.9)**

No MMR at 18 Months	**96.7 (78.6 to 99.5)**	**97.0 (88.6 to 99.3)**
MMR at 18 Months	**98.7 (91.2 to 99.8)**	**99.3 (95.2 to 99.9)**

No statistical analysis provided for Estimated Rates of Progression Free Survival (PFS) on Treatment by Major Molecular Response (MMR)

18. Secondary: Time to First Complete Molecular Response (CMR)] [Time Frame: 48 months overall]

Measure Type	Secondary
Measure Title	Time to First Complete Molecular Response (CMR)]
Measure Description	Complete Molecular Response is defined as a Bcr-Abl (a fusion of gene of Bcr and ABl genes) ratio ≤0.0032% on the International Scale Bcr = breakpoint cluster gene Abl = abelson proto-oncogene.
Time Frame	48 months overall
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.
This analysis was not done because no major molecular improvement was observed in the 800mg dose compared to 400mg dose. Hence, analysis for complete molecular response was not necessary.

Reporting Groups

	Description
Imatinib 400 mg	Oral dose of 400mg Imatinib once daily (q.d.). All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted, reduced, or escalated based on guidelines defined in protocol.

Imatinib 800 mg	Patients randomized to receive 800 mg Imatinib were to receive 400 mg twice daily (b.i.d.) oral administration, in the morning and the evening. All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted or reduced based on guidelines defined in protocol.

Measured Values

	Imatinib 400 mg	Imatinib 800 mg
Number of Participants Analyzed [units: participants]	**0**	**0**
Time to First Complete Molecular Response (CMR)] [units: Months] Median (95% Confidence Interval)		

No statistical analysis provided for Time to First Complete Molecular Response (CMR)]

19. Secondary: Number of Participants With the Effect of Imatinib on the Diabetic Participants With Known Concomitant Type II Diabetes [Time Frame: 12 months]

Measure Type	Secondary
Measure Title	Number of Participants With the Effect of Imatinib on the Diabetic Participants With Known Concomitant Type II Diabetes
Measure Description	No text entered.
Time Frame	12 months
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Due to the small number of diabetic patients enrolled into the study, the analysis was never done.

Reporting Groups

	Description
Imatinib 400 mg	Oral dose of 400mg Imatinib once daily (q.d.). All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted, reduced, or escalated based on guidelines defined in protocol.
Imatinib 800 mg	Patients randomized to receive 800 mg Imatinib were to receive 400 mg twice daily (b.i.d.) oral administration, in the morning and the evening. All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted or reduced based on guidelines defined in protocol.

Measured Values

	Imatinib 400 mg	Imatinib 800 mg
Number of Participants Analyzed [units: participants]	**0**	**0**
Number of Participants With the Effect of Imatinib on the Diabetic Participants With Known Concomitant Type II Diabetes [units: Participants]		

No statistical analysis provided for Number of Participants With the Effect of Imatinib on the Diabetic Participants With Known Concomitant Type II Diabetes

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Imatinib 400mg	Oral dose of 400mg imatinib once daily. All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted, reduced, or escalated based on guidelines defined in protocol.
Imatinib 800mg	Patients randomized to receive 800 mg imatinib were to receive 400 mg twice daily (b.i.d.) oral administration, in the morning and the evening. All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted or reduced based on guidelines defined in protocol.

Serious Adverse Events

	Imatinib 400mg	Imatinib 800mg
Total, serious adverse events		
# participants affected / at risk	**42/157 (26.75%)**	**121/316 (38.29%)**
Blood and lymphatic system disorders		
Anaemia † [1]		
# participants affected / at risk	**3/157 (1.91%)**	**6/316 (1.90%)**
Febrile neutropenia † [1]		
# participants affected / at risk	**2/157 (1.27%)**	**5/316 (1.58%)**
Granulocytopenia † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Leukopenia † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**2/316 (0.63%)**
Neutropenia † [1]		
# participants affected / at risk	**5/157 (3.18%)**	**12/316 (3.80%)**
Pancytopenia † [1]		
# participants affected / at risk	**1/157 (0.64%)**	**1/316 (0.32%)**
Splenic cyst † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**

Thrombocytopenia † [1]		
# participants affected / at risk	**4/157 (2.55%)**	**9/316 (2.85%)**
Cardiac disorders		
Angina pectoris † [1]		
# participants affected / at risk	**2/157 (1.27%)**	**0/316 (0.00%)**
Arrhythmia supraventricular † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Atrial fibrillation † [1]		
# participants affected / at risk	**1/157 (0.64%)**	**3/316 (0.95%)**
Cardiac arrest † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Cardiac discomfort † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Cardiac failure congestive † [1]		
# participants affected / at risk	**1/157 (0.64%)**	**1/316 (0.32%)**
Coronary artery disease † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Coronary artery occlusion † [1]		
# participants affected / at risk	**1/157 (0.64%)**	**0/316 (0.00%)**
Myocardial infarction † [1]		
# participants affected / at risk	**1/157 (0.64%)**	**1/316 (0.32%)**
Palpitations † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Congenital, familial and genetic disorders		
Phimosis † [1]		

# participants affected / at risk	1/157 (0.64%)	0/316 (0.00%)
Ear and labyrinth disorders		
Deafness † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Hearing impaired † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Sudden hearing loss † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Vertigo † 1		
# participants affected / at risk	1/157 (0.64%)	0/316 (0.00%)
Endocrine disorders		
Hypothyroidism † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Eye disorders		
Amaurosis † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Conjunctivitis † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Glaucoma † 1		
# participants affected / at risk	0/157 (0.00%)	2/316 (0.63%)
Retinal detachment † 1		
# participants affected / at risk	0/157 (0.00%)	2/316 (0.63%)
Retinal haemorrhage † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Retinal vein occlusion † 1		

# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Uveitis † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Vitreous haemorrhage † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Gastrointestinal disorders		
Abdominal pain † 1		
# participants affected / at risk	1/157 (0.64%)	3/316 (0.95%)
Abdominal pain lower † 1		
# participants affected / at risk	0/157 (0.00%)	3/316 (0.95%)
Abdominal pain upper † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Anal polyp † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Caecitis † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Colitis † 1		
# participants affected / at risk	0/157 (0.00%)	3/316 (0.95%)
Diarrhoea † 1		
# participants affected / at risk	1/157 (0.64%)	4/316 (1.27%)
Diverticulum † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Duodenal ulcer † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Enteritis † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)

Enterovesical fistula † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Gastritis † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**2/316 (0.63%)**
Gastritis alcoholic † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Gastrointestinal haemorrhage † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**3/316 (0.95%)**
Haematemesis † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Haemorrhoids † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**2/316 (0.63%)**
Hiatus hernia † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Inguinal hernia † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Lower gastrointestinal haemorrhage † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Melaena † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Nausea † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**3/316 (0.95%)**
Reflux gastritis † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Small intestinal haemorrhage † [1]		

# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Small intestinal obstruction † 1		
# participants affected / at risk	0/157 (0.00%)	2/316 (0.63%)
Upper gastrointestinal haemorrhage † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Vomiting † 1		
# participants affected / at risk	1/157 (0.64%)	4/316 (1.27%)
General disorders		
Adverse drug reaction † 1		
# participants affected / at risk	1/157 (0.64%)	0/316 (0.00%)
Asthenia † 1		
# participants affected / at risk	0/157 (0.00%)	2/316 (0.63%)
Chest discomfort † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Chest pain † 1		
# participants affected / at risk	2/157 (1.27%)	0/316 (0.00%)
Concomitant disease progression † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Death † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Device ineffective † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Mucosal inflammation † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Non-cardiac chest pain † 1		

# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Polyp † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Polyserositis † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Pyrexia † 1		
# participants affected / at risk	3/157 (1.91%)	13/316 (4.11%)
Hepatobiliary disorders		
Bile duct stone † 1		
# participants affected / at risk	1/157 (0.64%)	0/316 (0.00%)
Cholecystitis † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Cholecystitis acute † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Cholelithiasis † 1		
# participants affected / at risk	1/157 (0.64%)	2/316 (0.63%)
Hepatotoxicity † 1		
# participants affected / at risk	0/157 (0.00%)	2/316 (0.63%)
Liver disorder † 1		
# participants affected / at risk	1/157 (0.64%)	1/316 (0.32%)
Infections and infestations		
Appendicitis † 1		
# participants affected / at risk	0/157 (0.00%)	5/316 (1.58%)
Bacterial infection † 1		
# participants affected / at risk	1/157 (0.64%)	0/316 (0.00%)

Bacterial sepsis † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Cellulitis † 1		
# participants affected / at risk	**0/157 (0.00%)**	**2/316 (0.63%)**
Diverticulitis † 1		
# participants affected / at risk	**0/157 (0.00%)**	**3/316 (0.95%)**
Escherichia bacteraemia † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Febrile infection † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Gastroenteritis † 1		
# participants affected / at risk	**2/157 (1.27%)**	**5/316 (1.58%)**
Gastroenteritis viral † 1		
# participants affected / at risk	**1/157 (0.64%)**	**0/316 (0.00%)**
Gastrointestinal infection † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
HIV infection † 1		
# participants affected / at risk	**1/157 (0.64%)**	**0/316 (0.00%)**
Haematoma infection † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Herpes zoster † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Infection † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Influenza † 1		
# participants affected / at risk	**1/157 (0.64%)**	**0/316 (0.00%)**

Meningitis † [1]		
# participants affected / at risk	**1/157 (0.64%)**	**0/316 (0.00%)**
Pharyngotonsillitis † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Pneumonia † [1]		
# participants affected / at risk	**2/157 (1.27%)**	**5/316 (1.58%)**
Pneumonia pneumococcal † [1]		
# participants affected / at risk	**1/157 (0.64%)**	**0/316 (0.00%)**
Pulmonary tuberculosis † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Pyelonephritis † [1]		
# participants affected / at risk	**1/157 (0.64%)**	**1/316 (0.32%)**
Pyelonephritis acute † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Retroperitoneal abscess † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Salmonellosis † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**2/316 (0.63%)**
Sepsis † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Septic shock † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Sinusitis † [1]		
# participants affected / at risk	**1/157 (0.64%)**	**0/316 (0.00%)**
Tooth infection † [1]		

# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Upper respiratory tract infection † [1]		
# participants affected / at risk	1/157 (0.64%)	2/316 (0.63%)
Urinary tract infection † [1]		
# participants affected / at risk	1/157 (0.64%)	1/316 (0.32%)
Injury, poisoning and procedural complications		
Alcohol poisoning † [1]		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Ankle fracture † [1]		
# participants affected / at risk	2/157 (1.27%)	0/316 (0.00%)
Drug exposure during pregnancy † [1]		
# participants affected / at risk	1/157 (0.64%)	1/316 (0.32%)
Fall † [1]		
# participants affected / at risk	2/157 (1.27%)	2/316 (0.63%)
Hip fracture † [1]		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Injury † [1]		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Joint dislocation † [1]		
# participants affected / at risk	1/157 (0.64%)	0/316 (0.00%)
Joint injury † [1]		
# participants affected / at risk	1/157 (0.64%)	0/316 (0.00%)
Lower limb fracture † [1]		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Multiple fractures † [1]		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)

Subdural haematoma † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Tendon rupture † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Investigations		
Alanine aminotransferase increased † [1]		
# participants affected / at risk	**1/157 (0.64%)**	**1/316 (0.32%)**
Aspartate aminotransferase increased † [1]		
# participants affected / at risk	**1/157 (0.64%)**	**1/316 (0.32%)**
Electrocardiogram T wave abnormal † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Metabolism and nutrition disorders		
Decreased appetite † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Dehydration † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**2/316 (0.63%)**
Gout † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Hypocalcaemia † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Hypokalaemia † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Musculoskeletal and connective tissue disorders		
Arthralgia † [1]		
# participants affected / at risk	**1/157 (0.64%)**	**3/316 (0.95%)**

Back pain † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**3/316 (0.95%)**
Bone pain † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Bursitis † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Flank pain † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Intervertebral disc protrusion † [1]		
# participants affected / at risk	**1/157 (0.64%)**	**2/316 (0.63%)**
Musculoskeletal chest pain † [1]		
# participants affected / at risk	**1/157 (0.64%)**	**0/316 (0.00%)**
Musculoskeletal pain † [1]		
# participants affected / at risk	**1/157 (0.64%)**	**0/316 (0.00%)**
Myalgia † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**2/316 (0.63%)**
Myositis † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
B-cell lymphoma † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Basal cell carcinoma † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Bladder cancer † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**2/316 (0.63%)**

Bladder transitional cell carcinoma † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Blast crisis in myelogenous leukaemia † 1		
# participants affected / at risk	**2/157 (1.27%)**	**2/316 (0.63%)**
Breast cancer † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Chronic myeloid leukaemia † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Colorectal cancer † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Desmoid tumour † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Lung adenocarcinoma † 1		
# participants affected / at risk	**1/157 (0.64%)**	**0/316 (0.00%)**
Metastases to liver † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Mycosis fungoides † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Prostate cancer † 1		
# participants affected / at risk	**0/157 (0.00%)**	**5/316 (1.58%)**
Renal cell carcinoma † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Sarcoma † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Squamous cell carcinoma † 1		

# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Thyroid adenoma † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Thyroid cancer † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Uterine leiomyoma † 1		
# participants affected / at risk	1/157 (0.64%)	1/316 (0.32%)
Nervous system disorders		
Cerebral infarction † 1		
# participants affected / at risk	1/157 (0.64%)	0/316 (0.00%)
Cervical myelopathy † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Diabetic neuropathy † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Dizziness † 1		
# participants affected / at risk	1/157 (0.64%)	0/316 (0.00%)
Encephalopathy † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Epilepsy † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Headache † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
IIIrd nerve paralysis † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Migraine † 1		
# participants affected / at risk	1/157 (0.64%)	1/316 (0.32%)

Nerve root compression † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Paraesthesia † 1		
# participants affected / at risk	**0/157 (0.00%)**	**3/316 (0.95%)**
Parkinsonism † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Radiculopathy † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Spinal cord compression † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Subarachnoid haemorrhage † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Syncope † 1		
# participants affected / at risk	**0/157 (0.00%)**	**3/316 (0.95%)**
Transient ischaemic attack † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
VIIth nerve paralysis † 1		
# participants affected / at risk	**1/157 (0.64%)**	**0/316 (0.00%)**
Pregnancy, puerperium and perinatal conditions		
Abortion incomplete † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Neonatal disorder † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Placental disorder † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**

Pregnancy † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**2/316 (0.63%)**
Premature labour † [1]		
# participants affected / at risk	**1/157 (0.64%)**	**0/316 (0.00%)**
Psychiatric disorders		
Confusional state † [1]		
# participants affected / at risk	**1/157 (0.64%)**	**0/316 (0.00%)**
Depression † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**2/316 (0.63%)**
Renal and urinary disorders		
Calculus ureteric † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**3/316 (0.95%)**
Calculus urinary † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Haematuria † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Nephrolithiasis † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Paroxysmal nocturnal haemoglobinuria † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Renal colic † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Renal failure † [1]		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Renal failure acute † [1]		

# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Urethral disorder † 1		
# participants affected / at risk	1/157 (0.64%)	0/316 (0.00%)
Reproductive system and breast disorders		
Cervical dysplasia † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Endometriosis † 1		
# participants affected / at risk	1/157 (0.64%)	0/316 (0.00%)
Haemorrhagic ovarian cyst † 1		
# participants affected / at risk	1/157 (0.64%)	0/316 (0.00%)
Ovarian cyst ruptured † 1		
# participants affected / at risk	1/157 (0.64%)	0/316 (0.00%)
Prostatitis † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Respiratory, thoracic and mediastinal disorders		
Chronic obstructive pulmonary disease † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)
Cough † 1		
# participants affected / at risk	1/157 (0.64%)	1/316 (0.32%)
Dyspnoea † 1		
# participants affected / at risk	1/157 (0.64%)	4/316 (1.27%)
Epistaxis † 1		
# participants affected / at risk	1/157 (0.64%)	0/316 (0.00%)
Haemoptysis † 1		
# participants affected / at risk	0/157 (0.00%)	1/316 (0.32%)

Lung consolidation † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Oropharyngeal pain † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Pleural effusion † 1		
# participants affected / at risk	**1/157 (0.64%)**	**0/316 (0.00%)**
Pneumonitis † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Pulmonary embolism † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Respiratory failure † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Skin and subcutaneous tissue disorders		
Angioedema † 1		
# participants affected / at risk	**0/157 (0.00%)**	**2/316 (0.63%)**
Dermatitis allergic † 1		
# participants affected / at risk	**1/157 (0.64%)**	**0/316 (0.00%)**
Rash † 1		
# participants affected / at risk	**0/157 (0.00%)**	**4/316 (1.27%)**
Rash pruritic † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Skin lesion † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Toxic skin eruption † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**

Social circumstances		
Pregnancy of partner † 1		
# participants affected / at risk	**2/157 (1.27%)**	**2/316 (0.63%)**
Vascular disorders		
Circulatory collapse † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Extremity necrosis † 1		
# participants affected / at risk	**1/157 (0.64%)**	**0/316 (0.00%)**
Haematoma † 1		
# participants affected / at risk	**1/157 (0.64%)**	**0/316 (0.00%)**
Hypertensive crisis † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Hypotension † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Orthostatic hypotension † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Peripheral ischaemia † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**
Peripheral vascular disorder † 1		
# participants affected / at risk	**1/157 (0.64%)**	**0/316 (0.00%)**
Vasculitis † 1		
# participants affected / at risk	**0/157 (0.00%)**	**1/316 (0.32%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

Other Adverse Events

Hide Other Adverse Events

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

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Imatinib 400mg	Oral dose of 400mg imatinib once daily. All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted, reduced, or escalated based on guidelines defined in protocol.
Imatinib 800mg	Patients randomized to receive 800 mg imatinib were to receive 400 mg twice daily (b.i.d.) oral administration, in the morning and the evening. All patients received the assigned dose starting on Day 0 (Visit 3). The dose of Imatinib could be interrupted or reduced based on guidelines defined in protocol.

Other Adverse Events

	Imatinib 400mg	Imatinib 800mg
Total, other (not including serious) adverse events		
# participants affected / at risk	**157/157 (100.00%)**	**315/316 (99.68%)**
Blood and lymphatic system disorders		
Anaemia † [1]		
# participants affected / at risk	**41/157 (26.11%)**	**120/316 (37.97%)**
Leukopenia † [1]		
# participants affected / at risk	**20/157 (12.74%)**	**51/316 (16.14%)**
Neutropenia † [1]		

# participants affected / at risk	38/157 (24.20%)	107/316 (33.86%)
Thrombocytopenia † 1		
# participants affected / at risk	36/157 (22.93%)	111/316 (35.13%)
Eye disorders		
Conjunctival haemorrhage † 1		
# participants affected / at risk	8/157 (5.10%)	19/316 (6.01%)
Conjunctivitis † 1		
# participants affected / at risk	9/157 (5.73%)	19/316 (6.01%)
Eye swelling † 1		
# participants affected / at risk	3/157 (1.91%)	19/316 (6.01%)
Eyelid oedema † 1		
# participants affected / at risk	21/157 (13.38%)	45/316 (14.24%)
Lacrimation increased † 1		
# participants affected / at risk	8/157 (5.10%)	30/316 (9.49%)
Periorbital oedema † 1		
# participants affected / at risk	46/157 (29.30%)	132/316 (41.77%)
Gastrointestinal disorders		
Abdominal discomfort † 1		
# participants affected / at risk	13/157 (8.28%)	17/316 (5.38%)
Abdominal distension † 1		
# participants affected / at risk	9/157 (5.73%)	15/316 (4.75%)
Abdominal pain † 1		
# participants affected / at risk	36/157 (22.93%)	76/316 (24.05%)
Abdominal pain upper † 1		
# participants affected / at risk	38/157 (24.20%)	54/316 (17.09%)

Constipation † 1		
# participants affected / at risk	**19/157 (12.10%)**	**36/316 (11.39%)**
Diarrhoea † 1		
# participants affected / at risk	**71/157 (45.22%)**	**184/316 (58.23%)**
Dyspepsia † 1		
# participants affected / at risk	**21/157 (13.38%)**	**57/316 (18.04%)**
Flatulence † 1		
# participants affected / at risk	**7/157 (4.46%)**	**20/316 (6.33%)**
Gastritis † 1		
# participants affected / at risk	**6/157 (3.82%)**	**20/316 (6.33%)**
Gastrooesophageal reflux disease † 1		
# participants affected / at risk	**5/157 (3.18%)**	**28/316 (8.86%)**
Haemorrhoids † 1		
# participants affected / at risk	**6/157 (3.82%)**	**25/316 (7.91%)**
Nausea † 1		
# participants affected / at risk	**78/157 (49.68%)**	**205/316 (64.87%)**
Toothache † 1		
# participants affected / at risk	**14/157 (8.92%)**	**21/316 (6.65%)**
Vomiting † 1		
# participants affected / at risk	**54/157 (34.39%)**	**140/316 (44.30%)**
General disorders		
Asthenia † 1		
# participants affected / at risk	**22/157 (14.01%)**	**48/316 (15.19%)**
Chest pain † 1		
# participants affected / at risk	**9/157 (5.73%)**	**7/316 (2.22%)**

Chills † 1		
# participants affected / at risk	**9/157 (5.73%)**	**18/316 (5.70%)**
Face oedema † 1		
# participants affected / at risk	**13/157 (8.28%)**	**64/316 (20.25%)**
Fatigue † 1		
# participants affected / at risk	**51/157 (32.48%)**	**131/316 (41.46%)**
Influenza like illness † 1		
# participants affected / at risk	**12/157 (7.64%)**	**35/316 (11.08%)**
Oedema † 1		
# participants affected / at risk	**10/157 (6.37%)**	**35/316 (11.08%)**
Oedema peripheral † 1		
# participants affected / at risk	**43/157 (27.39%)**	**135/316 (42.72%)**
Pyrexia † 1		
# participants affected / at risk	**31/157 (19.75%)**	**75/316 (23.73%)**
Infections and infestations		
Bronchitis † 1		
# participants affected / at risk	**10/157 (6.37%)**	**26/316 (8.23%)**
Gastroenteritis † 1		
# participants affected / at risk	**8/157 (5.10%)**	**26/316 (8.23%)**
Influenza † 1		
# participants affected / at risk	**17/157 (10.83%)**	**18/316 (5.70%)**
Nasopharyngitis † 1		
# participants affected / at risk	**19/157 (12.10%)**	**30/316 (9.49%)**
Pharyngitis † 1		
# participants affected / at risk	**5/157 (3.18%)**	**17/316 (5.38%)**

Sinusitis † [1]		
# participants affected / at risk	13/157 (8.28%)	33/316 (10.44%)
Upper respiratory tract infection † [1]		
# participants affected / at risk	44/157 (28.03%)	88/316 (27.85%)
Urinary tract infection † [1]		
# participants affected / at risk	17/157 (10.83%)	26/316 (8.23%)
Injury, poisoning and procedural complications		
Contusion † [1]		
# participants affected / at risk	6/157 (3.82%)	18/316 (5.70%)
Procedural pain † [1]		
# participants affected / at risk	7/157 (4.46%)	16/316 (5.06%)
Investigations		
Alanine aminotransferase increased † [1]		
# participants affected / at risk	11/157 (7.01%)	25/316 (7.91%)
Aspartate aminotransferase increased † [1]		
# participants affected / at risk	11/157 (7.01%)	26/316 (8.23%)
Platelet count decreased † [1]		
# participants affected / at risk	1/157 (0.64%)	18/316 (5.70%)
Weight decreased † [1]		
# participants affected / at risk	6/157 (3.82%)	26/316 (8.23%)
Weight increased † [1]		
# participants affected / at risk	26/157 (16.56%)	54/316 (17.09%)
Metabolism and nutrition disorders		
Decreased appetite † [1]		
# participants affected / at risk	22/157 (14.01%)	54/316 (17.09%)

Fluid retention † [1]		
# participants affected / at risk	**3/157 (1.91%)**	**21/316 (6.65%)**
Hypocalcaemia † [1]		
# participants affected / at risk	**8/157 (5.10%)**	**28/316 (8.86%)**
Hypokalaemia † [1]		
# participants affected / at risk	**8/157 (5.10%)**	**33/316 (10.44%)**
Hypophosphataemia † [1]		
# participants affected / at risk	**30/157 (19.11%)**	**43/316 (13.61%)**
Musculoskeletal and connective tissue disorders		
Arthralgia † [1]		
# participants affected / at risk	**48/157 (30.57%)**	**107/316 (33.86%)**
Back pain † [1]		
# participants affected / at risk	**29/157 (18.47%)**	**71/316 (22.47%)**
Bone pain † [1]		
# participants affected / at risk	**17/157 (10.83%)**	**39/316 (12.34%)**
Flank pain † [1]		
# participants affected / at risk	**2/157 (1.27%)**	**16/316 (5.06%)**
Muscle spasms † [1]		
# participants affected / at risk	**69/157 (43.95%)**	**141/316 (44.62%)**
Musculoskeletal chest pain † [1]		
# participants affected / at risk	**10/157 (6.37%)**	**14/316 (4.43%)**
Musculoskeletal pain † [1]		
# participants affected / at risk	**22/157 (14.01%)**	**29/316 (9.18%)**
Myalgia † [1]		
# participants affected / at risk	**37/157 (23.57%)**	**83/316 (26.27%)**

Neck pain † [1]		
# participants affected / at risk	**10/157 (6.37%)**	**16/316 (5.06%)**
Pain in extremity † [1]		
# participants affected / at risk	**33/157 (21.02%)**	**79/316 (25.00%)**
Nervous system disorders		
Dizziness † [1]		
# participants affected / at risk	**38/157 (24.20%)**	**47/316 (14.87%)**
Dysgeusia † [1]		
# participants affected / at risk	**8/157 (5.10%)**	**37/316 (11.71%)**
Headache † [1]		
# participants affected / at risk	**46/157 (29.30%)**	**98/316 (31.01%)**
Paraesthesia † [1]		
# participants affected / at risk	**11/157 (7.01%)**	**16/316 (5.06%)**
Psychiatric disorders		
Anxiety † [1]		
# participants affected / at risk	**12/157 (7.64%)**	**24/316 (7.59%)**
Depression † [1]		
# participants affected / at risk	**20/157 (12.74%)**	**32/316 (10.13%)**
Insomnia † [1]		
# participants affected / at risk	**21/157 (13.38%)**	**53/316 (16.77%)**
Respiratory, thoracic and mediastinal disorders		
Cough † [1]		
# participants affected / at risk	**34/157 (21.66%)**	**74/316 (23.42%)**
Dyspnoea † [1]		
# participants affected / at risk	**10/157 (6.37%)**	**44/316 (13.92%)**

Epistaxis † 1		
# participants affected / at risk	**8/157 (5.10%)**	**21/316 (6.65%)**
Oropharyngeal pain † 1		
# participants affected / at risk	**13/157 (8.28%)**	**27/316 (8.54%)**
Skin and subcutaneous tissue disorders		
Alopecia † 1		
# participants affected / at risk	**9/157 (5.73%)**	**38/316 (12.03%)**
Dry skin † 1		
# participants affected / at risk	**4/157 (2.55%)**	**18/316 (5.70%)**
Night sweats † 1		
# participants affected / at risk	**18/157 (11.46%)**	**25/316 (7.91%)**
Pruritus † 1		
# participants affected / at risk	**15/157 (9.55%)**	**41/316 (12.97%)**
Rash † 1		
# participants affected / at risk	**32/157 (20.38%)**	**119/316 (37.66%)**
Vascular disorders		
Hypertension † 1		
# participants affected / at risk	**12/157 (7.64%)**	**18/316 (5.70%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

More Information

Hide More Information

Certain Agreements:

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

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

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial.

Results Point of Contact:

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

No publications provided by Novartis

Publications automatically indexed to this study:

Branford S, Yeung DT, Ross DM, Prime JA, Field CR, Altamura HK, Yeoman AL, Georgievski J, Jamison BA, Phillis S, Sullivan B, Briggs NE, Hertzberg M, Seymour JF, Reynolds J, Hughes TP. Early molecular response and female sex strongly predict stable undetectable BCR-ABL1, the criteria for imatinib discontinuation in patients with CML. Blood. 2013 May 9;121(19):3818-24. doi: 10.1182/blood-2012-10-462291. Epub 2013 Mar 20.

Guilhot F, Hughes TP, Cortes J, Druker BJ, Baccarani M, Gathmann I, Hayes M, Granvil C, Wang Y. Plasma exposure of imatinib and its correlation with clinical response in the Tyrosine Kinase Inhibitor Optimization and Selectivity Trial. Haematologica. 2012 May;97(5):731-8. doi: 10.3324/haematol.2011.045666. Epub 2012 Feb 7.

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