Results Registration Form

NCT00726232

Point of Contact

Name or Official Title:	Study Director
Organization Name:	Incyte Corporation
Phone:	1-855-463-3463
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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.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.
Following the first publication, the Institution and/or Principal Investigator may publish data or results from the Study; provided, however, that the Institution and/or Principal Investigator submits the proposed publication to the Sponsor for review at least sixty (60) days prior to the date of the proposed publication. Sponsor may remove from the proposed publication any information that is considered confidential and/or proprietary other than Study data and results.

Participant Flow

Recruitment Details	This was a multicenter study with 2 sites in the United States and 4 sites in Italy.
Pre-assignment Details	

Type of Units Assigned:

Period: Initial phase (dose-finding)

	Polycythemia Vera (PV): Ruxolitinib 10 mg BID Participants with Polycythemia Vera received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib 25 mg BID** Participants with Polycythemia Vera received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib 50 mg QD** Participants with Polycythemia Vera received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**Essential Thrombocythemia (ET): Ruxolitinib 10 mg BID** Participants with Essential Thrombocythemia received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 25 mg BID** Participants with Essential Thrombocythemia received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 50 mg QD** Participants with Essential Thrombocythemia received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib All Doses Combined-Expansion Phase** After the completion of the dose-finding phase of the study, the starting dose of ruxolitinib for the expansion phase was determined to be 10 mg BID for subjects with PV. After subjects completed 8 weeks of ruxolitinib treatment at the starting dose, investigators were permitted to adjust the dose regimen to a maximum total daily dose of 75 mg on an individual basis, using their discretion, in order to achieve an optimal balance of efficacy and safety.	**ET: Ruxolitinib All Doses Combined-expansion Phase** After the completion of the dose-finding phase of the study, the starting dose of ruxolitinib for the expansion phase was determined to be 25 mg BID for subjects with ET. After subjects completed 8 weeks of ruxolitinib treatment at the starting dose, investigators were permitted to adjust the dose regimen to a maximum total daily dose of 75 mg on an individual basis, using their discretion, in order to achieve an optimal balance of efficacy and safety.	**Total** *(=sum per row)*
Started	Participants 19 The starting dose selected for the PV expansion cohort was 10 mg bid hence the sample size is larger	Participants 8	Participants 7	Participants 8	Participants 22 The starting dose selected for the ET expansion cohort was 25 mg bid hence the sample size is larger	Participants 9	Participants 0	Participants 0	73 *(calculated)*
Safety evaluable participants	Participants 19	Participants 8	Participants 7	Participants 8	Participants 22	Participants 9	Participants 0	Participants 0	73 *(calculated)*
ITT participants	Participants 19	Participants 8	Participants 7	Participants 8	Participants 22	Participants 9	Participants 0	Participants 0	73 *(calculated)*
Completed Represents participants ongoing treatment.	Participants 6	Participants 2	Participants 2	Participants 0	Participants 1	Participants 0	Participants 0	Participants 0	11 *(calculated)*
Not Completed: *(=Started - Completed)*	13 *(calculated)*	6 *(calculated)*	5 *(calculated)*	8 *(calculated)*	21 *(calculated)*	9 *(calculated)*	0 *(calculated)*	0 *(calculated)*	62 *(calculated)*
Reason for Not Completed									

Total: *(=sum per column)*	13 *(calculated)*	6 *(calculated)*	5 *(calculated)*	8 *(calculated)*	21 *(calculated)*	9 *(calculated)*	0 *(calculated)*	0 *(calculated)*	62 *(calculated)*
Death	0	0	0	0	1	0	0	0	1 *(calculated)*
Adverse Event	2	2	2	1	7	3	0	0	17 *(calculated)*
Withdrawal by Subject	2	0	0	1	0	2	0	0	5 *(calculated)*
Other Disease progression	3	1	0	0	0	0	0	0	4 *(calculated)*
Other Termination of the trial by sponsor	4	3	3	4	9	3	0	0	26 *(calculated)*
Other Per Investigator: lack of response	1	0	0	2	4	1	0	0	8 *(calculated)*
Other Unspecified reason	1	0	0	0	0	0	0	0	1 *(calculated)*

Period: Expansion Phase

	Polycythemia Vera (PV): Ruxolitinib 10 mg BID Participants with Polycythemia Vera received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib 25 mg BID** Participants with Polycythemia Vera received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib 50 mg QD** Participants with Polycythemia Vera received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**Essential Thrombocythemia (ET): Ruxolitinib 10 mg BID** Participants with Essential Thrombocythemia received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 25 mg BID** Participants with Essential Thrombocythemia received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 50 mg QD** Participants with Essential Thrombocythemia received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib All Doses Combined-Expansion Phase** After the completion of the dose-finding phase of the study, the starting dose of ruxolitinib for the expansion phase was determined to be 10 mg BID for subjects with PV. After subjects completed 8 weeks of ruxolitinib treatment at the starting dose, investigators were permitted to adjust the dose regimen to a maximum total daily dose of 75 mg on an individual basis, using their discretion, in order to achieve an optimal balance of efficacy and safety.	**ET: Ruxolitinib All Doses Combined-expansion Phase** After the completion of the dose-finding phase of the study, the starting dose of ruxolitinib for the expansion phase was determined to be 25 mg BID for subjects with ET. After subjects completed 8 weeks of ruxolitinib treatment at the starting dose, investigators were permitted to adjust the dose regimen to a maximum total daily dose of 75 mg on an individual basis, using their discretion, in order to achieve an optimal balance of efficacy and safety.	**Total** *(=sum per row)*
Started	Participants 0 NOTE: The number of participants to start a Period is not equal to the number who completed previous Period.	Participants 0 NOTE: The number of participants to start a Period is not equal to the number who completed previous Period.	Participants 0 NOTE: The number of participants to start a Period is not equal to the number who completed previous Period.	Participants 0	Participants 0 NOTE: The number of participants to start a Period is not equal to the number who completed previous Period.	Participants 0	Participants 34 NOTE: The number of participants to start a Period is not equal to the number who completed previous Period.	Participants 39 NOTE: The number of participants to start a Period is not equal to the number who completed previous Period.	73 *(calculated)*
Safety evaluable participants	Participants 0	Participants 0	Participants 0	Participants 0	Participants 0	Participants 0	Participants 34	Participants 39	73 *(calculated)*
ITT participants	Participants 0	Participants 0	Participants 0	Participants 0	Participants 0	Participants 0	Participants 34	Participants 39	73 *(calculated)*
Completed Participants ongoing: last patient last visit (LPLV) occurred 20AUG2018 following the data cutoff.	Participants 0	Participants 0	Participants 0	Participants 0	Participants 0	Participants 0	Participants 10	Participants 1	11 *(calculated)*

Not Completed: *(=Started - Completed)*	0 *(calculated)*	0 *(calculated)*	0 *(calculated)*	0 *(calculated)*	0 *(calculated)*	0 *(calculated)*	24 *(calculated)*	38 *(calculated)*	62 *(calculated)*
Reason for Not Completed									
Total: *(=sum per column)*	0 *(calculated)*	0 *(calculated)*	0 *(calculated)*	0 *(calculated)*	0 *(calculated)*	0 *(calculated)*	24 *(calculated)*	38 *(calculated)*	62 *(calculated)*
Death	0	0	0	0	0	0	0	1	1 *(calculated)*
Adverse Event	0	0	0	0	0	0	6	11	17 *(calculated)*
Withdrawal by Subject	0	0	0	0	0	0	2	3	5 *(calculated)*
Other Disease progression	0	0	0	0	0	0	4	0	4 *(calculated)*
Other Termination of the trial by sponsor	0	0	0	0	0	0	10	16	26 *(calculated)*
Other Per Investigator: lack of response	0	0	0	0	0	0	1	7	8 *(calculated)*
Other Unspecified reason	0	0	0	0	0	0	1	0	1 *(calculated)*

Baseline Characteristics

Overall Number of Baseline Participants							
	PV: Ruxolitinib 10 mg BID Participants with Polycythemia Vera received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib 25 mg BID** Participants with Polycythemia Vera received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib 50 mg QD** Participants with Polycythemia Vera received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 10 mg BID** Participants with Essential Thrombocythemia received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 25 mg BID** Participants with Essential Thrombocythemia received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 50 mg QD** Participants with Essential Thrombocythemia received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**Total(=sum across Arm/Groups)**
Overall Number of Baseline	19	8	7	8	22	9	73

Participants								*(calculated)*
Overall Number Of Units Analyzed **Type Of Units Analyzed**:								Unknown *(calculated)*
Baseline Analysis Population Description	Safety evaluable PV and ET participants.The safety evaluable population included all enrolled participants who received at lease 1 dose of study drug.							

Baseline measure title = "Age Continuous"

Age Continuous
Units: years
Parameter type: Mean
Dispersion type: Standard Deviation

Row	Category	**PV: Ruxolitinib 10 mg BID** Participants with Polycythemia Vera received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib 25 mg BID** Participants with Polycythemia Vera received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib 50 mg QD** Participants with Polycythemia Vera received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 10 mg BID** Participants with Essential Thrombocythemia received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 25 mg BID** Participants with Essential Thrombocythemia received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 50 mg QD** Participants with Essential Thrombocythemia received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**Total**
Polycythemia vera group	Number Analyzed:	19 Participants	8 Participants	7 Participants	8 Participants	22 Participants	9 Participants	73 *(calculated)* Participants
		56.3 (10.98)	57.0 (11.26)	51.0 (20.49)	N/A Age demographic data for the polycythemia vera group. (N/A)	N/A Age demographic data for the polycythemia vera group. (N/A)	N/A Age demographic data for the polycythemia vera group. (N/A)	55.4 (13.20)
Essential thrombocythemia group	Number Analyzed:	19 Participants	8 Participants	7 Participants	8 Participants	22 Participants	9 Participants	73 *(calculated)* Participants
		N/A Age demographic data for the essential thrombocythemia group. (N/A)	N/A Age demographic data for the essential thrombocythemia group. (N/A)	N/A Age demographic data for the essential thrombocythemia group. (N/A)	49.6 (17.89)	54.1 (11.55)	52.8 (13.48)	52.9 (13.19)

Baseline measure title = "Age, Customized"

Age, Customized

Parameter type: Count of Participants
HINT: Number is the preferred Measure Type for Age, Customized
Dispersion type: Not Applicable

Row	Category	**PV: Ruxolitinib 10 mg BID** Participants with Polycythemia Vera received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib 25 mg BID** Participants with Polycythemia Vera received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib 50 mg QD** Participants with Polycythemia Vera received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 10 mg BID** Participants with Essential Thrombocythemia received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 25 mg BID** Participants with Essential Thrombocythemia received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 50 mg QD** Participants with Essential Thrombocythemia received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**Total** *(=sum per row)*
>= 65	Number Analyzed:	19 Participants	8 Participants	7 Participants	8 Participants	22 Participants	9 Participants	73 *(calculated)* Participants
		5	3	2	1	3	3	17 *(calculated)*
< 65	Number Analyzed:	19 Participants	8 Participants	7 Participants	8 Participants	22 Participants	9 Participants	73 *(calculated)* Participants
		14	5	5	7	19	6	56 *(calculated)*

HINT: Number is the preferred Measure Type for Age, Customized

Baseline measure title = "Gender, Male/Female"

Sex: Female, Male
Parameter type: Count of Participants
Dispersion type: Not Applicable

Row	Category	**PV: Ruxolitinib 10 mg BID** Participants with Polycythemia Vera received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of	**PV: Ruxolitinib 25 mg BID** Participants with Polycythemia Vera received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of	**PV: Ruxolitinib 50 mg QD** Participants with Polycythemia Vera received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of	**ET: Ruxolitinib 10 mg BID** Participants with Essential Thrombocythemia received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of	**ET: Ruxolitinib 25 mg BID** Participants with Essential Thrombocythemia received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of	**ET: Ruxolitinib 50 mg QD** Participants with Essential Thrombocythemia received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of	**Total** *(=sum per row)*

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	Number Analyzed:	19 Participants	8 Participants	7 Participants	8 Participants	22 Participants	9 Participants	73 *(calculated)* Participants
	Female	11	2	4	3	13	9	42 *(calculated)*
	Male	8	6	3	5	9	0	31 *(calculated)*

Baseline measure title = "Study Specific Characteristic"

Study Specific Characteristic
Hematocrit
Parameter type: Count of Participants
Dispersion type: Not Applicable

Row	Category	**PV: Ruxolitinib 10 mg BID** Participants with Polycythemia Vera received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib 25 mg BID** Participants with Polycythemia Vera received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib 50 mg QD** Participants with Polycythemia Vera received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 10 mg BID** Participants with Essential Thrombocythemia received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 25 mg BID** Participants with Essential Thrombocythemia received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 50 mg QD** Participants with Essential Thrombocythemia received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**Total** *(=sum per row)*
Hematocrit ≥ 45%	Number Analyzed:	19 Participants	8 Participants	7 Participants	8 Participants	22 Participants	9 Participants	73 *(calculated)* Participants

		10	7	6	1	4	0	28 *(calculated)*
Hematocrit < 45%	Number Analyzed:	19 Participants	8 Participants	7 Participants	8 Participants	22 Participants	9 Participants	73 *(calculated)* Participants
		9	1	1	7	18	9	45 *(calculated)*

Baseline measure title = "Study Specific Characteristic"

Study Specific Characteristic
Platelet count
Parameter type: Count of Participants
Dispersion type: Not Applicable

Row	Category	**PV: Ruxolitinib 10 mg BID** Participants with Polycythemia Vera received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib 25 mg BID** Participants with Polycythemia Vera received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib 50 mg QD** Participants with Polycythemia Vera received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 10 mg BID** Participants with Essential Thrombocythemia received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 25 mg BID** Participants with Essential Thrombocythemia received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 50 mg QD** Participants with Essential Thrombocythemia received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**Total** *(=sum per row)*
≥400 x 10^9 per liter	Number Analyzed:	19 Participants	8 Participants	7 Participants	8 Participants	22 Participants	9 Participants	73 *(calculated)* Participants
		13	4	6	7	22	9	61 *(calculated)*
< 400 x 10^9 per liter	Number Analyzed:	19 Participants	8 Participants	7 Participants	8 Participants	22 Participants	9 Participants	73 *(calculated)* Participants
		6	4	1	1	0	0	12 *(calculated)*

Baseline measure title = "Study Specific Characteristic"

Study Specific Characteristic
White blood cell count
Parameter type: Count of Participants
Dispersion type: Not Applicable

Row	Category	**PV: Ruxolitinib**	**PV: Ruxolitinib**	**PV: Ruxolitinib**	**ET: Ruxolitinib**	**ET: Ruxolitinib**	**ET: Ruxolitinib**	**Total**

		10 mg BID Participants with Polycythemia Vera received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**25 mg BID** Participants with Polycythemia Vera received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**50 mg QD** Participants with Polycythemia Vera received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**10 mg BID** Participants with Essential Thrombocythemia received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**25 mg BID** Participants with Essential Thrombocythemia received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**50 mg QD** Participants with Essential Thrombocythemia received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	*(=sum per row)*
≥ 10 x 10^9 per liter	Number Analyzed:	19 Participants	8 Participants	7 Participants	8 Participants	22 Participants	9 Participants	73 *(calculated)* Participants
		12	7	6	2	7	2	36 *(calculated)*
< 10 x 10^9 per liter	Number Analyzed:	19 Participants	8 Participants	7 Participants	8 Participants	22 Participants	9 Participants	73 *(calculated)* Participants
		7	1	1	6	15	7	37 *(calculated)*

Outcome Measures

ALERT: Outcome measures from protocol are not used when records include results.

1. Primary: Percentage of Polycythemia Vera participants with a confirmed clinical Partial Response (PR) or Complete Response (CR)

Reporting Status:

Description: For a confirmed response all criteria must have been sustained for at least 2 months. CR: -Hematocrit < 45% in men and < 42% in women -No phlebotomy for 1 month -No palpable splenomegaly -White blood cells < 10 x 10^9/L with normal differential and platelets < 400 x 10^9/L -No sustained leucopenia or thrombocytopenia (>2 weeks) -No systemic PV symptoms (pruritus, night sweats, bone pain, fever, weight loss) PR: -Hematocrit < 45% in men and < 42% in women -50% reduction in phlebotomy requirements from 6 months before treatment started -50% reduction in palpable splenomegaly

Time Frame: Assessed after 2 cycles (56 days) of treatment on Day 1 of Cycle 3

Safety Issue:

Measure Type: Number

Method of Dispersion: Not Applicable

Unit of Measure: percentage of participants

Type of Units Analyzed:

Analysis Population Description: Polycythemia Vera intent to treat population, including all patients who took at least 1 dose of study drug.

		PV: Ruxolitinib 10 mg BID Participants with Polycythemia Vera received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib 25 mg BID** Participants with Polycythemia Vera received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib 50 mg QD** Participants with Polycythemia Vera received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.
	Number of Participants Analyzed:	19	8	7
Percentage of Polycythemia Vera participants with a confirmed clinical Partial Response (PR) or Complete Response (CR) Units: percentage of participants	Category	Number	Number	Number
	Number Analyzed: NOTE: Number Analyzed row will not be displayed in PRS when single Measure Row.	19 Participants	8 Participants	7 Participants
		58	50	57

2. Primary: Percentage of Essential Thrombocythemia (ET) participants with a confirmed clinical Partial Response (PR) or Complete Response (CR)

Reporting Status:

Description: For a confirmed response all criteria must have been sustained for at least 2 months. Complete Clinical Response: -Platelet count < 400 x 10^9/L -White blood cell count < 10 x 10^9/L with normal differential and Hematocrit ≤ upper limit of normal -Absence of sustained (> 2 weeks) anemia or leucopenia based on institutional normal ranges -Absence of systemic ET symptoms (pruritus, bone pain, weakness, night sweats, paresthesias) -Absence of palpable splenomegaly Partial Clinical Response: -Platelet count < 400 x 10^9/L -50% reduction in palpable splenomegaly

Time Frame: Assessed after 2 cycles (56 days) of treatment on Day 1 of Cycle 3.

Safety Issue:

Measure Type: Number

Method of Dispersion: Not Applicable

Unit of Measure: percentage of participants

Type of

Units Analyzed:

Analysis Population Description: Essential thrombocythemia intent to treat population, including all patients who took at least 1 dose of study drug. One patient in the 50 mg QD group did not have a response assessment at Cycle 3, Day 1.

		ET: Ruxolitinib 10 mg BID Participants with Essential Thrombocythemia received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 25 mg BID** Participants with Essential Thrombocythemia received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 50 mg QD** Participants with Essential Thrombocythemia received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.
	Number of Participants Analyzed:	8	22	8
Percentage of Essential Thrombocythemia (ET) participants with a confirmed clinical Partial Response (PR) or Complete Response (CR) Units: percentage of participants	Category	Number	Number	Number
	Number Analyzed: NOTE: Number Analyzed row will not be displayed in PRS when single Measure Row.	8 Participants	22 Participants	8 Participants
		13	0	0

3. Secondary: Percentage of Polycythemia Vera Participants who achieved individual components of clinical response at 12 weeks

Reporting Status:

Description: The individual components of clinical response included: -Hematocrit (Hct) < 45% without phlebotomy -Absence of palpable splenomegaly -50% reduction in spleen size -Platelet count ≤ 400 x 10^9/L -White blood cell (WBC) count ≤ 10 x 10^9/L

Time Frame: Baseline and Week 12 (Cycle 4, Day 1)

Safety Issue:

Measure Type: Number

Method of Dispersion: Not Applicable

Unit of Measure: percentage of participants

Type of Units Analyzed:

Analysis Population Description: Polycythemia Vera intent to treat population for whom data was available.

	PV: Ruxolitinib 10 mg BID Participants with	**PV: Ruxolitinib 25 mg BID** Participants with	**PV: Ruxolitinib 50 mg QD** Participants with

		Polycythemia Vera received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	Polycythemia Vera received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	Polycythemia Vera received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.
	Number of Participants Analyzed:	19	8	7
Percentage of Polycythemia Vera Participants who achieved individual components of clinical response at 12 weeks Units: percentage of participants	Category	Number	Number	Number
Hematocrit <45% Without Phlebotomy	Number Analyzed:	19 Participants	8 Participants	7 Participants
		95	88	86
Absence of palpable splenomegaly	Number Analyzed:	19 Participants	8 Participants	7 Participants
		68	50	57
50% reduction in spleen size	Number Analyzed:	19 Participants	8 Participants	7 Participants
		74	63	86
Platelet count ≤ 400 x 10^9/L	Number Analyzed:	19 Participants	8 Participants	7 Participants
		58	50	57
WBC count ≤ 10 x 10^9/L	Number Analyzed:	19 Participants	8 Participants	7 Participants
		68	63	43

4. Secondary: Percentage of Polycythemia Vera Participants who achieved individual components of clinical response at 24 weeks

Reporting Status:

Description: The individual components of clinical response included: -Hematocrit (Hct) < 45% without phlebotomy -Absence of palpable splenomegaly -50% reduction in spleen size -Platelet count ≤ 400 x 10^9/L -White blood cell (WBC) count ≤ 10 x 10^9/L

Time Frame: Baseline and Week 24 (Cycle 7, Day 1)

Safety Issue:

Measure Type: Number

Method of Dispersion: Not Applicable

Unit of Measure: percentage of participants

Type of Units Analyzed:

Analysis Population Description: Polycythemia Vera intent to treat population for whom data was available. 'N' indicates the number of patients for whom data was available for each component.

		PV: Ruxolitinib 10 mg BID Participants with Polycythemia Vera received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib 25 mg BID** Participants with Polycythemia Vera received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib 50 mg QD** Participants with Polycythemia Vera received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.
	Number of Participants Analyzed:	19	8	7
Percentage of Polycythemia Vera Participants who achieved individual components of clinical response at 24 weeks Units: percentage of participants	Category	Number	Number	Number
Hematocrit <45% Without Phlebotomy	Number Analyzed:	19 Participants	8 Participants	7 Participants
		100	88	100
Absence of palpable splenomegaly	Number Analyzed:	18 Participants	7 Participants	7 Participants
		61	43	71
50% reduction in spleen size	Number Analyzed:	18 Participants	7 Participants	7 Participants
		78	71	100
Platelet count ≤ 400 x 10^9/L	Number Analyzed:	19 Participants	8 Participants	7 Participants
		58	88	86
WBC count ≤ 10 x 10^9/L	Number Analyzed:	19 Participants	8 Participants	7 Participants
		74	25	86

5. Secondary: Percentage of Polycythemia Vera Participants who achieved individual components of clinical response at 36 weeks

Reporting Status:

Description: The individual components of clinical response included: -Hematocrit (Hct) < 45% without phlebotomy -Absence of palpable splenomegaly -50% reduction in spleen size -Platelet count ≤ 400 x 10^9/L -White blood cell (WBC) count ≤ 10 x 10^9/L

Time Frame: Baseline and Week 36 (Cycle 10, Day 1)

Safety Issue:

Measure Type: Number

Method of Dispersion: Not Applicable

Unit of Measure: percentage of participants

Type of Units Analyzed:

Analysis Population Description: Polycythemia Vera intent to treat population for whom data was available. 'N' indicates the number of patients for whom data was available for each component.

		PV: Ruxolitinib 10 mg BID Participants with Polycythemia Vera received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib 25 mg BID** Participants with Polycythemia Vera received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib 50 mg QD** Participants with Polycythemia Vera received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.
	Number of Participants Analyzed:	18	8	7
Percentage of Polycythemia Vera Participants who achieved individual components of clinical response at 36 weeks Units: percentage of participants	Category	Number	Number	Number
Hematocrit <45% Without Phlebotomy	Number Analyzed:	18 Participants	8 Participants	7 Participants
		100	88	100
Absence of palpable splenomegaly	Number Analyzed:	17 Participants	7 Participants	7 Participants
		71	57	86
50% reduction in spleen size	Number Analyzed:	17 Participants	7 Participants	7 Participants
		76	71	100
Platelet count ≤ 400 x 10^9/L	Number Analyzed:	18 Participants	8 Participants	7 Participants

		67	75	86
WBC count ≤ 10 x 10^9/L	Number Analyzed:	18 Participants	8 Participants	7 Participants
		67	25	71

6. Secondary: Percentage of Essential Thrombocythemia Participants Who Achieved Individual Components of Clinical Response at 4 Weeks

Reporting Status:

Description: The individual components of clinical response included: -Platelet count ≤ 400 x 10^9/L -White blood cell (WBC) count ≤ 10 x 10^9/L -50% reduction in spleen size -Absence of palpable splenomegaly

Time Frame: Baseline and 4 weeks (Cycle 2, Day 1)

Safety Issue:

Measure Type: Number

Method of Dispersion: Not Applicable

Unit of Measure: percentage of participants

Type of Units Analyzed:

Analysis Population Description: Essential thrombocythemia intent to treat population. 'N' indicates the number of patients for whom data was available for each component.

		ET: Ruxolitinib 10 mg BID Participants with Essential Thrombocythemia received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 25 mg BID** Participants with Essential Thrombocythemia received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 50 mg QD** Participants with Essential Thrombocythemia received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.
	Number of Participants Analyzed:	8	22	9
Percentage of Essential Thrombocythemia Participants Who Achieved Individual Components of Clinical Response at 4 Weeks Units: percentage of participants	Category	Number	Number	Number
Platelet count ≤ 400 x 10^9/L	Number Analyzed:	8 Participants	22 Participants	9 Participants
		25	41	33

WBC count ≤ 10 x 10^9/L	Number Analyzed:	8 Participants	22 Participants	9 Participants
		100	100	100
50% reduction in spleen size	Number Analyzed:	6 Participants	19 Participants	8 Participants
		83	95	100
Absence of palpable splenomegaly	Number Analyzed:	6 Participants	19 Participants	8 Participants
		67	89	100

7. Secondary: Percentage of Essential Thrombocythemia Participants Who Achieved Individual Components of Clinical Response at 24 Weeks

Reporting Status:	
Description:	The individual components of clinical response included: -Platelet count ≤ 400 x 10^9/L -White blood cell (WBC) count ≤ 10 x 10^9/L -50% reduction in spleen size -Absence of palpable splenomegaly
Time Frame:	Baseline and 24 weeks (Cycle 7, Day 1)
Safety Issue:	
Measure Type:	Number
Method of Dispersion:	Not Applicable
Unit of Measure:	percentage of participants
Type of Units Analyzed:	
Analysis Population Description:	Essential thrombocythemia intent to treat population. 'N' indicates the number of patients for whom data was available for each component.

		ET: Ruxolitinib 10 mg BID Participants with Essential Thrombocythemia received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 25 mg BID** Participants with Essential Thrombocythemia received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 50 mg QD** Participants with Essential Thrombocythemia received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.
	Number of Participants Analyzed:	8	22	9
Percentage of Essential Thrombocythemia Participants Who Achieved Individual Components of Clinical Response at 24 Weeks	Category	Number	Number	Number

Units: percentage of participants				
Platelet count ≤ 400 x 10^9/L	Number Analyzed:	7 Participants	21 Participants	8 Participants
		14	5	0
WBC count ≤ 10 x 10^9/L	Number Analyzed:	7 Participants	21 Participants	8 Participants
		100	86	100
50% reduction in spleen size	Number Analyzed:	6 Participants	19 Participants	7 Participants
		100	100	100
Absence of palpable splenomegaly	Number Analyzed:	6 Participants	19 Participants	7 Participants
		100	95	100

8. Secondary: Percentage of Essential Thrombocythemia Participants Who Achieved Individual Components of Clinical Response at 36 Weeks

Reporting Status:

Description: The individual components of clinical response included: -Platelet count ≤ 400 x 10^9/L -White blood cell (WBC) count ≤ 10 x 10^9/L -50% reduction in spleen size -Absence of palpable splenomegaly

Time Frame: Baseline and 36 weeks (Cycle 10, Day 1)

Safety Issue:

Measure Type: Number

Method of Dispersion: Not Applicable

Unit of Measure: percentage of participants

Type of Units Analyzed:

Analysis Population Description: Essential thrombocythemia intent to treat population. 'N' indicates the number of patients for whom data was available for each component.

	ET: Ruxolitinib 10 mg BID Participants with Essential Thrombocythemia received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression	**ET: Ruxolitinib 25 mg BID** Participants with Essential Thrombocythemia received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression	**ET: Ruxolitinib 50 mg QD** Participants with Essential Thrombocythemia received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression

		of disease, or withdrew consent.	of disease, or withdrew consent.	of disease, or withdrew consent.
	Number of Participants Analyzed:	8	22	9
Percentage of Essential Thrombocythemia Participants Who Achieved Individual Components of Clinical Response at 36 Weeks Units: percentage of participants	Category	Number	Number	Number
Platelet count ≤ 400 x 10^9/L	Number Analyzed:	7 Participants	19 Participants	7 Participants
		14	11	14
WBC count ≤ 10 x 10^9/L	Number Analyzed:	7 Participants	19 Participants	7 Participants
		100	79	86
50% reduction in spleen size	Number Analyzed:	6 Participants	16 Participants	6 Participants
		100	100	100
Absence of palpable splenomegaly	Number Analyzed:	6 Participants	16 Participants	6 Participants
		100	94	100

9. Secondary: Change from Baseline to Week 4 in Polycythemia Vera Symptoms

Reporting Status:

Description: Patients were asked to rate their symptoms on a scale of 0 (none) to 10 (worse possible) for the prior week giving the worst level of symptoms experienced during the preceding 7 days. A negative change from baseline score indicates improvement in symptoms. For patients with Polycythemia Vera, queried symptoms included fever, itching/pruritus, bone pain and night sweats.

Time Frame: Baseline and Week 4 (Cycle 2, Day 1)

Safety Issue:

Measure Type: Mean

Method of Dispersion: Standard Deviation

Unit of Measure: scores on a scale

Type of Units Analyzed:

Analysis Population Description: Polycythemia Vera intent to treat population who had symptom scores > 0 at baseline for whom data was available.

	PV: Ruxolitinib 10 mg BID Participants with Polycythemia Vera received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment	**PV: Ruxolitinib 25 mg BID** Participants with Polycythemia Vera received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment	**PV: Ruxolitinib 50 mg QD** Participants with Polycythemia Vera received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment

		continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.		continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.		continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	
	Number of Participants Analyzed:	19		8		7	
Change from Baseline to Week 4 in Polycythemia Vera Symptoms Units: scores on a scale	Category	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
Itching (pruritus)	Number Analyzed:	13 Participants		8 Participants		5 Participants	
		-4.2	3.63	-4.6	1.85	-2.8	4.09
Bone pain	Number Analyzed:	12 Participants		2 Participants		3 Participants	
		-2.0	1.95	-2.5	0.71	-4.3	2.08
Fever	Number Analyzed:	2 Participants		0 Participants		2 Participants	
		-2.0	1.41			-2.0	1.41
Night sweats	Number Analyzed:	9 Participants		6 Participants		3 Participants	
		-1.9	2.52	-2.8	3.19	-3.3	1.15

10. Secondary: Change from Baseline to Week 4 in essential Thrombocythemia symptoms

Reporting Status:

Description: Patients were asked to rate their symptoms on a scale of 0 (none) to 10 (worse possible) for the prior week giving the worst level of symptoms experienced during the preceding 7 days. A negative change from baseline score indicates improvement in symptoms. For patients with essential thrombocythemia, queried symptoms included itching/pruritus, bone pain, night sweats, paresthesias (tingling or numbness), and weakness.

Time Frame: Baseline and Week 4 (Cycle 2, Day 1)

Safety Issue:

Measure Type: Mean

Method of Dispersion: Standard Deviation

Unit of Measure: score on a scale

Type of Units Analyzed:

Analysis Population Description: Essential Thrombocythemia intent to treat population who had symptom scores > 0 at baseline and for whom data was available.

	ET: Ruxolitinib 10 mg BID Participants with Essential Thrombocythemia received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles	**ET: Ruxolitinib 25 mg BID** Participants with Essential Thrombocythemia received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles	**ET: Ruxolitinib 50 mg QD** Participants with Essential Thrombocythemia received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of

		of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.		of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.		treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	
	Number of Participants Analyzed:	8		22		8	
Change from Baseline to Week 4 in essential Thrombocythemia symptoms Units: score on a scale	Category	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
Itching (pruritus)	Number Analyzed:	3 Participants		10 Participants		0 Participants	
		-2.7	2.89	-1.2	2.74		
Night Sweats	Number Analyzed:	1 Participants		8 Participants		3 Participants	
		-5.0	N/A	-1.3	2.49	-4.0	4.36
		Only one patient available for this analysis					
Weakness	Number Analyzed:	3 Participants		14 Participants		3 Participants	
		-1.0	1.00	-0.2	2.46	-1.7	2.52
Bone pain	Number Analyzed:	2 Participants		13 Participants		3 Participants	
		-3.5	2.12	-0.4	2.26	-2.3	4.93
Paresthesia	Number Analyzed:	3 Participants		14 Participants		6 Participants	
		-1.7	2.08	-1.6	1.50	-2.8	2.93

11. Secondary: Change from Baseline to week 4 in Health-related Quality of Life

Reporting Status:

Description: Health-related Quality of Life was assessed using the Global Health Status/Quality of Life Scale of the European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30). This scale ranges from 0 to 100, with higher scores indicating higher quality of life.

Time Frame: Baseline and Week 4 (Cycle 2, Day 1)

Safety Issue:

Measure Type: Mean

Method of Dispersion: Standard Deviation

Unit of Measure: units on a scale

Type of Units Analyzed:

Analysis Population Intent to treat population. The intent-to-treat (ITT) population included all subjects who took at least 1 dose of study drug.

Description:

		PV: Ruxolitinib 10 mg BID Participants with Polycythemia Vera received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.		**PV: Ruxolitinib 25 mg BID** Participants with Polycythemia Vera received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.		**PV: Ruxolitinib 50 mg QD** Participants with Polycythemia Vera received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.		**ET: Ruxolitinib 10 mg BID** Participants with Essential Thrombocythemia received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.		**ET: Ruxolitinib 25 mg BID** Participants with Essential Thrombocythemia received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.		**ET: Ruxolitinib 50 mg QD** Participants with Essential Thrombocythemia received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	
	Number of Participants Analyzed:	19		8		7		8		22		9	
Change from Baseline to week 4 in Health-related Quality of Life Units: units on a scale	Category	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
	Number Analyzed: NOTE: Number Analyzed row will not be displayed in PRS when single Measure Row.	19 Participants		8 Participants		7 Participants		8 Participants		22 Participants		9 Participants	
		10.9	10.80	6.3	14.0	14.6	17.78	-2.1	10.5	3.0	27.6	11.2	23.4

Limitations and Caveats

Description	The study was terminated by the clinical trial sponsor.

Adverse Events

Time Frame	From start of study up to data cutoff at 20 June 2018; approximately 9 years.
Adverse Event Reporting Description	Safety evaluable PV and ET participants.The safety evaluable

	population included all enrolled participants who received at lease 1 dose of study drug.
Source Vocabulary for Table Default	MedDRA (Unspecified)
Collection Approach for Table Default	Systematic Assessment

All-Cause Mortality

	PV: Ruxolitinib 10 mg BID Participants with Polycythemia Vera received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib 25 mg BID** Participants with Polycythemia Vera received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib 50 mg QD** Participants with Polycythemia Vera received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 10 mg BID** Participants with Essential Thrombocythemia received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 25 mg BID** Participants with Essential Thrombocythemia received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 50 mg QD** Participants with Essential Thrombocythemia received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib All doses combined-expansion phase** After the completion of the dose-finding phase of the study, the starting dose of ruxolitinib for the expansion phase was determined to be 10 mg BID for subjects with PV. After subjects completed 8 weeks of ruxolitinib treatment at the starting dose, investigators were permitted to adjust the dose regimen to a maximum total daily dose of 75 mg on an individual basis, using their discretion, in order to achieve an optimal balance of efficacy and safety.	**ET: Ruxolitinib All doses combined-expansion phase** After the completion of the dose-finding phase of the study, the starting dose of ruxolitinib for the expansion phase was determined to be 25 mg BID for subjects with ET. After subjects completed 8 weeks of ruxolitinib treatment at the starting dose, investigators were permitted to adjust the dose regimen to a maximum total daily dose of 75 mg on an individual basis, using their discretion, in order to achieve an optimal balance of efficacy and safety.
Total Number Affected								
Total Number At Risk								

Serious Adverse Events

	PV: Ruxolitinib 10 mg BID Participants with Polycythemia Vera received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients	**PV: Ruxolitinib 25 mg BID** Participants with Polycythemia Vera received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients	**PV: Ruxolitinib 50 mg QD** Participants with Polycythemia Vera received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients	**ET: Ruxolitinib 10 mg BID** Participants with Essential Thrombocythemia received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were	**ET: Ruxolitinib 25 mg BID** Participants with Essential Thrombocythemia received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were	**ET: Ruxolitinib 50 mg QD** Participants with Essential Thrombocythemia received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were	**PV: Ruxolitinib All doses combined-expansion phase** After the completion of the dose-finding phase of the study, the starting dose of ruxolitinib for the expansion phase was determined to	**ET: Ruxolitinib All doses combined-expansion phase** After the completion of the dose-finding phase of the study, the starting dose of ruxolitinib for the expansion phase was determined to

	completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	be 10 mg BID for subjects with PV. After subjects completed 8 weeks of ruxolitinib treatment at the starting dose, investigators were permitted to adjust the dose regimen to a maximum total daily dose of 75 mg on an individual basis, using their discretion, in order to achieve an optimal balance of efficacy and safety.	be 25 mg BID for subjects with ET. After subjects completed 8 weeks of ruxolitinib treatment at the starting dose, investigators were permitted to adjust the dose regimen to a maximum total daily dose of 75 mg on an individual basis, using their discretion, in order to achieve an optimal balance of efficacy and safety.
Total # Affected by any Serious Adverse Event	2	2	1	1	1	3	17	17
Total # at Risk by any Serious Adverse Event	19	8	7	8	22	9	34	39

	Blood and lymphatic system disorders							
Anaemia[1, †]								
Number of participants affected	1	0	0	0	0	0	1	0
Number of events								
Number of participants at risk [blank=Total]								
Thrombocytopenia[1, †]								
Number of participants affected	1	0	0	0	0	0	1	0
Number of events								
Number of participants at risk [blank=Total]								

	Cardiac disorders							
Atrial flutter[1, †]								
Number of participants affected	1	0	0	0	0	0	1	0
Number of events								
Number of participants at risk [blank=Total]								
Cardiac failure congestive[1, †]								
Number of participants affected	0	0	1	0	0	0	1	1

Number of events								
Number of participants at risk [blank=Total]								
Atrial fibrillation[1, †]								
Number of participants affected	0	0	0	0	0	0	1	0
Number of events								
Number of participants at risk [blank=Total]								
Mitral valve incompetence[1, †]								
Number of participants affected	0	0	0	0	0	0	1	0
Number of events								
Number of participants at risk [blank=Total]								
Cardiac failure[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								
Ventricular tachycardia[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								

	Gastrointestinal disorders							
Gastric varices haemorrhage[1, †]								
Number of participants affected	1	0	0	0	0	0	1	0
Number of events								
Number of participants at risk [blank=Total]								
Gastrointestinal haemorrhage[1, †]								
Number of participants affected	0	0	0	0	0	1	0	1
Number of events								
Number of participants at risk [blank=Total]								
Haematemesis[1, †]								
Number of participants affected	0	0	0	0	0	0	1	0
Number of events								
Number of participants at risk [blank=Total]								

Ileus[1, †]								
Number of participants affected	0	0	0	0	0	0	1	0
Number of events								
Number of participants at risk [blank=Total]								
Inguinal hernia[1, †]								
Number of participants affected	0	0	0	0	0	0	1	0
Number of events								
Number of participants at risk [blank=Total]								
Varices oesophageal[1, †]								
Number of participants affected	0	0	0	0	0	0	1	1
Number of events								
Number of participants at risk [blank=Total]								
Erosive oesophagitis[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								
Gastric haemorrhage[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								
Retroperitoneal haematoma[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								
Small intestine ulcer[1, †]								
Number of participants affected	0	0	0	0	0	0	00	1
Number of events								
Number of participants at risk [blank=Total]								

	Hepatobiliary disorders							
Cholecystitis[1, †]								
Number of participants affected	0	0	0	0	1	0	0	1

Number of events								
Number of participants at risk [blank=Total]								

	Infections and infestations							
Pneumonia[1, †]								
Number of participants affected	0	1	1	0	0	0	3	2
Number of events								
Number of participants at risk [blank=Total]								
Bronchitis[1, †]								
Number of participants affected	0	0	0	0	0	1	0	1
Number of events								
Number of participants at risk [blank=Total]								
Abdominal abscess[1, †]								
Number of participants affected	0	0	0	0	0	0	1	0
Number of events								
Number of participants at risk [blank=Total]								
Gastroenteritis[1, †]								
Number of participants affected	0	0	0	0	0	0	1	0
Number of events								
Number of participants at risk [blank=Total]								
Postoperative wound infection[1, †]								
Number of participants affected	0	0	0	0	0	0	1	0
Number of events								
Number of participants at risk [blank=Total]								
Progressive multifocal leukoencephalopathy[1, †]								
Number of participants affected	0	0	0	0	0	0	1	0
Number of events								
Number of participants at risk [blank=Total]								
Urinary tract infection[1, †]								
Number of participants affected	0	0	0	0	0	0	1	0
Number of events								
Number of participants at risk [blank=Total]								

Erysipelas[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								
Lung infection[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								
Pneumococcal bacteraemia[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								

	Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Renal neoplasm[1, †]								
Number of participants affected	0	1	0	0	0	0	1	0
Number of events								
Number of participants at risk [blank=Total]								
Squamous cell carcinoma[1, †]								
Number of participants affected	0	0	0	0	0	0	1	0
Number of events								
Number of participants at risk [blank=Total]								
Squamous cell carcinoma of the oral cavity[1, †]								
Number of participants affected	0	0	0	0	0	0	1	0
Number of events								
Number of participants at risk [blank=Total]								
Squamous cell carcinoma of the tongue[1, †]								
Number of participants affected	0	0	0	0	0	0	1	0
Number of events								
Number of participants at risk [blank=Total]								
Tongue cancer recurrent[1, †]								
Number of participants affected	0	00	0	0	0	0	1	0

Number of events								
Number of participants at risk [blank=Total]								
Acute leukaemia[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								
Basal cell carcinoma[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								
Chronic myeloid leukaemia[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								
Kaposi's sarcoma[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								
Metastases to bone[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								
Paget's disease of the vulva[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								
Skin cancer[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								

	Nervous system disorders

Headache[1, †]								
Number of participants affected	0	0	0	0	0	1	0	1
Number of events								
Number of participants at risk [blank=Total]								
Ischaemic stroke[1, †]								
Number of participants affected	0	0	0	0	0	0	1	0
Number of events								
Number of participants at risk [blank=Total]								
Transient ischaemic attack[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								
Cerebrovascular accident[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								

	Renal and urinary disorders							
Renal failure[1, †]								
Number of participants affected	0	0	0	1	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								
Nephrolithiasis[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								

	General disorders							
Non-cardiac chest pain[1, †]								
Number of participants affected	0	0	0	0	0	0	1	0
Number of events								
Number of participants at risk [blank=Total]								
Drug withdrawal syndrome[1, †]								

Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								
Multiple organ dysfunction syndrome[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								
Oedema peripheral[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								

	Injury, poisoning and procedural complications							
Accidental overdose[1, †]								
Number of participants affected	0	0	0	0	0	0	1	0
Number of events								
Number of participants at risk [blank=Total]								
Road traffic accident[1, †]								
Number of participants affected	0	0	0	0	0	0	1	0
Number of events								
Number of participants at risk [blank=Total]								
Traumatic intracranial haemorrhage[1, †]								
Number of participants affected	0	0	0	0	0	0	1	0
Number of events								
Number of participants at risk [blank=Total]								
Upper limb fracture[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								

	Musculoskeletal and connective tissue disorders							
Osteoarthritis[1, †]								
Number of participants affected	0	0	0	0	0	0	2	1

Number of events								
Number of participants at risk [blank=Total]								
Arthralgia[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								
Osteitis deformans[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								

	Reproductive system and breast disorders							
Ovarian cyst[1, †]								
Number of participants affected	0	0	0	0	0	0	1	0
Number of events								
Number of participants at risk [blank=Total]								

	Respiratory, thoracic and mediastinal disorders							
Pneumonitis[1, †]								
Number of participants affected	0	0	0	0	0	0	1	0
Number of events								
Number of participants at risk [blank=Total]								
Pulmonary embolism[1, †]								
Number of participants affected	0	0	0	0	0	0	2	1
Number of events								
Number of participants at risk [blank=Total]								
Dyspnoea[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								

	Metabolism and nutrition disorders							
Hyperuricaemia[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1

Number of events								
Number of participants at risk [blank=Total]								

	Vascular disorders							
Hypotension[1, †]								
Number of participants affected	0	0	0	0	0	0	0	1
Number of events								
Number of participants at risk [blank=Total]								

†	Events were collected by systematic assessment
1	Term from vocabulary, *MedDRA (Unspecified)*

Other Adverse Events

Frequency Threshold for reporting Other Adverse Events: 5

	PV: Ruxolitinib 10 mg BID Participants with Polycythemia Vera received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib 25 mg BID** Participants with Polycythemia Vera received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib 50 mg QD** Participants with Polycythemia Vera received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 10 mg BID** Participants with Essential Thrombocythemia received 10 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 25 mg BID** Participants with Essential Thrombocythemia received 25 mg Ruxolitinib orally twice a day (BID) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**ET: Ruxolitinib 50 mg QD** Participants with Essential Thrombocythemia received 50 mg Ruxolitinib orally once a day (QD) for 56 days (two 28-day cycles) during the dose-ranging phase. After patients completed 2 cycles of treatment at the randomized dose, Investigators were permitted to adjust the dose/regimen on an individual basis to achieve an optimal balance of efficacy and safety. Treatment continued until a patient met a withdrawal criterion, had intolerable toxicity, progression of disease, or withdrew consent.	**PV: Ruxolitinib All doses combined-expansion phase** After the completion of the dose-finding phase of the study, the starting dose of ruxolitinib for the expansion phase was determined to be 10 mg BID for subjects with PV. After subjects completed 8 weeks of ruxolitinib treatment at the starting dose, investigators were permitted to adjust the dose regimen to a maximum total daily dose of 75 mg on an individual basis, using their discretion, in order to achieve an optimal balance of efficacy and safety.	**ET: Ruxolitinib All doses combined-expansion phase** After the completion of the dose-finding phase of the study, the starting dose of ruxolitinib for the expansion phase was determined to be 25 mg BID for subjects with ET. After subjects completed 8 weeks of ruxolitinib treatment at the starting dose, investigators were permitted to adjust the dose regimen to a maximum total daily dose of 75 mg on an individual basis, using their discretion, in order to achieve an optimal balance of efficacy and safety.
Total # Affected by any Other Adverse Event	19	8	7	8	22	8	34	39

Total # at Risk by any Other Adverse Event	19	8	7	8	22	9	34	39

	Blood and lymphatic system disorders							
Anaemia[1, †]								
Number of participants affected	16	6	3	5	19	6	27	32
Number of events								
Number of participants at risk [blank=Total]								
Thrombocytopenia[1, †]								
Number of participants affected	6	4	1	0	0	0	17	0
Number of events								
Number of participants at risk [blank=Total]								
Leukopenia[1, †]								
Number of participants affected	4	1	0	0	2	0	8	2
Number of events								
Number of participants at risk [blank=Total]								
Lymphadenitis[1, †]								
Number of participants affected	0	0	1	0	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								
Neutropenia[1, †]								
Number of participants affected	1	0	0	0	0	0	2	2
Number of events								
Number of participants at risk [blank=Total]								
Increased tendency to bruise[1, †]								
Number of participants affected	0	0	0	0	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								

	Cardiac disorders							
Palpitations[1, †]								
Number of participants affected	2	0	1	0	4	0	4	6
Number of events								

Number of participants at risk [blank=Total]								
Arrhythmia supraventricular[1, †]								
Number of participants affected	1	0	0	0	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								
Atrial fibrillation[1, †]								
Number of participants affected	1	0	0	0	0	0	3	0
Number of events								
Number of participants at risk [blank=Total]								
Supraventricular tachycardia[1, †]								
Number of participants affected	1	0	0	0	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								
Tachycardia[1, †]								
Number of participants affected	0	0	0	0	1	1	0	3
Number of events								
Number of participants at risk [blank=Total]								
Cardiac failure[1, †]								
Number of participants affected	0	0	0	1	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								

	Ear and labyrinth disorders							
Ear pain[1, †]								
Number of participants affected	0	0	1	0	0	1	2	0
Number of events								
Number of participants at risk [blank=Total]								
Tinnitus[1, †]								
Number of participants affected	0	0	0	0	0	0	2	0
Number of events								
Number of participants at risk [blank=Total]								
Vertigo[1, †]								

Number of participants affected	0	0	0	0	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								

	Endocrine disorders							
Goitre[1, †]								
Number of participants affected	0	0	0	0	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								
thyroid mass[1, †]								
Number of participants affected	0	0	0	00	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								

	Eye disorders							
Conjunctivitis[1, †]								
Number of participants affected	1	0	1	0	0	0	3	0
Number of events								
Number of participants at risk [blank=Total]								
Conjunctival haemorrhage[1, †]								
Number of participants affected	1	0	0	0	0	0	2	0
Number of events								
Number of participants at risk [blank=Total]								
Eye pain[1, †]								
Number of participants affected	1	0	0	0	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								
Myodesopsia[1, †]								
Number of participants affected	1	0	0	0	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								
Photophobia[1, †]								
Number of participants affected	1	0	0	0	0	0	0	0

Number of events								
Number of participants at risk [blank=Total]								
Vision blurred[1, †]								
Number of participants affected	0	1	0	0	0	0	3	0
Number of events								
Number of participants at risk [blank=Total]								
Visual impairment[1, †]								
Number of participants affected	0	0	0	0	2	0	0	0
Number of events								
Number of participants at risk [blank=Total]								
Cataract[1, †]								
Number of participants affected	0	0	0	0	0	0	3	2
Number of events								
Number of participants at risk [blank=Total]								
Dry eye[1, †]								
Number of participants affected	0	0	0	0	0	0	2	0
Number of events								
Number of participants at risk [blank=Total]								
Vitreous floaters[1, †]								
Number of participants affected	0	0	0	0	0	0	2	0
Number of events								
Number of participants at risk [blank=Total]								
Photopsia[1, †]								
Number of participants affected	0	0	0	0	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								

	Gastrointestinal disorders							
Diarrhoea[1, †]								
Number of participants affected	4	2	1	1	4	3	12	12
Number of events								
Number of participants at risk [blank=Total]								

Vomiting[1, †]								
Number of participants affected	3	1	1	0	1	3	9	7
Number of events								
Number of participants at risk [blank=Total]								
Abdominal pain[1, †]								
Number of participants affected	2	1	1	0	2	0	6	3
Number of events								
Number of participants at risk [blank=Total]								
Constipation[1, †]								
Number of participants affected	0	1	1	0	4	1	4	6
Number of events								
Number of participants at risk [blank=Total]								
Abdominal pain upper[1, †]								
Number of participants affected	0	1	0	1	2	0	6	5
Number of events								
Number of participants at risk [blank=Total]								
Aphthous stomatitis[1, †]								
Number of participants affected	0	1	0	0	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								
Dental discomfort[1, †]								
Number of participants affected	0	0	1	0	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								
Gastrointestinal disorder[1, †]								
Number of participants affected	1	0	0	0	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								
Gastrooesophageal reflux disease[1, †]								
Number of participants affected	1	0	0	0	0	0	0	0
Number of events								

Number of participants at risk [blank=Total]								
Nausea[1, †]								
Number of participants affected	0	1	0	1	2	2	4	9
Number of events								
Number of participants at risk [blank=Total]								
Toothache[1, †]								
Number of participants affected	0	0	1	0	0	1	4	4
Number of events								
Number of participants at risk [blank=Total]								
Abdominal pain lower[1, †]								
Number of participants affected	0	0	0	1	0	1	0	2
Number of events								
Number of participants at risk [blank=Total]								
Dyspepsia[1, †]								
Number of participants affected	0	0	0	0	2	0	3	5
Number of events								
Number of participants at risk [blank=Total]								
Diverticulum[1, †]								
Number of participants affected	0	0	0	1	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								
Aphthous ulcer[1, †]								
Number of participants affected	0	0	0	0	0	0	2	0
Number of events								
Number of participants at risk [blank=Total]								
Gastrointestinal haemorrhage[1, †]								
Number of participants affected	0	0	0	0	0	0	2	0
Number of events								
Number of participants at risk [blank=Total]								
Abdominal distension[1, †]								
Number of participants affected	0	0	0	0	0	0	0	3

Number of events								
Number of participants at risk [blank=Total]								

	General disorders							
Influenza like illness[1, †]								
Number of participants affected	0	0	0	0	0	0	4	3
Number of events								
Number of participants at risk [blank=Total]								
Non-cardiac chest pain[1, †]								
Number of participants affected	0	0	0	0	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								
Peripheral swelling[1, †]								
Number of participants affected	0	0	0	0	0	0	0	3
Number of events								
Number of participants at risk [blank=Total]								

	General disorders and administration site conditions							
Pyrexia[1, †]								
Number of participants affected	4	1	1	2	4	1	13	16
Number of events								
Number of participants at risk [blank=Total]								
Asthenia[1, †]								
Number of participants affected	2	2	0	0	1	1	9	7
Number of events								
Number of participants at risk [blank=Total]								
Fatigue[1, †]								
Number of participants affected	1	0	1	0	2	2	5	5
Number of events								
Number of participants at risk [blank=Total]								
Oedema peripheral[1, †]								
Number of participants affected	1	1	0	1	0	0	4	5
Number of events								

Number of participants at risk [blank=Total]								
Chest pain[1, †]								
Number of participants affected	1	0	0	0	0	0	2	2
Number of events								
Number of participants at risk [blank=Total]								
Mucosal inflammation[1, †]								
Number of participants affected	0	0	1	0	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								

	Hepatobiliary disorders							
Hyperbilirubinaemia[1, †]								
Number of participants affected	0	0	2	1	0	0	2	0
Number of events								
Number of participants at risk [blank=Total]								

	Infections and infestations							
Herpes zoster[1, †]								
Number of participants affected	2	1	1	1	1	1	8	8
Number of events								
Number of participants at risk [blank=Total]								
Upper respiratory tract infection[1, †]								
Number of participants affected	1	1	2	0	2	0	9	4
Number of events								
Number of participants at risk [blank=Total]								
Influenza[1, †]								
Number of participants affected	0	2	1	0	0	0	8	4
Number of events								
Number of participants at risk [blank=Total]								
Cystitis[1, †]								
Number of participants affected	1	1	0	1	1	1	7	6
Number of events								
Number of participants at risk								

[blank=Total]								
Gastroenteritis[1, †]								
Number of participants affected	1	0	1	0	1	1	4	4
Number of events								
Number of participants at risk [blank=Total]								
Oral herpes[1, †]								
Number of participants affected	1	0	1	0	0	0	5	0
Number of events								
Number of participants at risk [blank=Total]								
Pharyngitis[1, †]								
Number of participants affected	2	0	0	0	0	0	3	5
Number of events								
Number of participants at risk [blank=Total]								
Bronchitis[1, †]								
Number of participants affected	0	1	0	2	1	0	9	11
Number of events								
Number of participants at risk [blank=Total]								
Ear infection[1, †]								
Number of participants affected	0	0	1	0	0	0	3	3
Number of events								
Number of participants at risk [blank=Total]								
Epstein-Barr virus infection[1, †]								
Number of participants affected	1	0	0	0	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								
Respiratory tract infection[1, †]								
Number of participants affected	0	1	0	0	0	1	0	0
Number of events								
Number of participants at risk [blank=Total]								
Rhinitis[1, †]								
Number of participants affected	0	1	0	1	0	0	2	0
Number of events								

Number of participants at risk [blank=Total]								
Sinusitis[1, †]								
Number of participants affected	1	0	0	0	0	1	2	3
Number of events								
Number of participants at risk [blank=Total]								
Tooth infection[1, †]								
Number of participants affected	1	0	0	0	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								
Vulvovaginal mycotic infection[1, †]								
Number of participants affected	1	0	0	0	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								
Tooth abscess[1, †]								
Number of participants affected	0	0	0	0	0	1	3	0
Number of events								
Number of participants at risk [blank=Total]								
Folliculitis[1, †]								
Number of participants affected	0	0	0	0	0	0	2	0
Number of events								
Number of participants at risk [blank=Total]								
Nasopharyngitis[1, †]								
Number of participants affected	0	0	0	0	0	0	3	2
Number of events								
Number of participants at risk [blank=Total]								
Urinary tract infection[1, †]								
Number of participants affected	0	0	0	0	0	0	3	4
Number of events								
Number of participants at risk [blank=Total]								
Vulvovaginal candidiasis[1, †]								
Number of	0	0	0	0	0	0	2	0

participants affected								
Number of events								
Number of participants at risk [blank=Total]								
Onychomycosis[1, †]								
Number of participants affected	0	0	0	0	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								
Pneumonia[1, †]								
Number of participants affected	0	0	0	0	0	0	0	3
Number of events								
Number of participants at risk [blank=Total]								
Tracheitis[1, †]								
Number of participants affected	0	0	0	0	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								

	Injury, poisoning and procedural complications							
Foot fracture[1, †]								
Number of participants affected	0	0	1	0	0	0	2	0
Number of events								
Number of participants at risk [blank=Total]								
Patella fracture[1, †]								
Number of participants affected	0	0	0	0	0	1	0	0
Number of events								
Number of participants at risk [blank=Total]								
Fall[1, †]								
Number of participants affected	0	0	0	0	0	0	2	6
Number of events								
Number of participants at risk [blank=Total]								
Hand fracture[1, †]								
Number of participants affected	0	0	0	0	0	0	2	0
Number of events								
Number of participants at risk								

[blank=Total]								
Contusion[1, †]								
Number of participants affected	0	0	0	0	0	0	0	3
Number of events								
Number of participants at risk [blank=Total]								
Limb injury[1, †]								
Number of participants affected	0	0	0	0	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								

	Investigations							
Weight increased[1, †]								
Number of participants affected	2	1	2	2	5	3	7	14
Number of events								
Number of participants at risk [blank=Total]								
Blood creatinine increased[1, †]								
Number of participants affected	1	1	1	0	0	2	3	3
Number of events								
Number of participants at risk [blank=Total]								
Alanine aminotransferase increased[1, †]								
Number of participants affected	1	0	0	0	0	0	4	3
Number of events								
Number of participants at risk [blank=Total]								
Aspartate aminotransferase increased[1, †]								
Number of participants affected	1	0	0	0	0	1	4	4
Number of events								
Number of participants at risk [blank=Total]								
Gamma-glutamyltransferase increased[1, †]								
Number of participants affected	1	0	0	0	0	0	6	2
Number of events								
Number of participants at risk [blank=Total]								
Transaminases increased[1, †]								
Number of	0	1	0	0	0	0	0	0

participants affected								
Number of events								
Number of participants at risk [blank=Total]								
Blood creatine phosphokinase increased[1, †]								
Number of participants affected	0	0	0	1	1	0	4	11
Number of events								
Number of participants at risk [blank=Total]								
Haematocrit decreased[1, †]								
Number of participants affected	0	0	0	1	0	0	0	3
Number of events								
Number of participants at risk [blank=Total]								
Blood glucose decreased[1, †]								
Number of participants affected	0	0	0	0	0	0	2	0
Number of events								
Number of participants at risk [blank=Total]								
Blood lactate dehydrogenase increased[1, †]								
Number of participants affected	0	0	0	0	0	0	2	2
Number of events								
Number of participants at risk [blank=Total]								
Cardiac murmur[1, †]								
Number of participants affected	0	0	0	0	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								
Platelet count increased[1, †]								
Number of participants affected	0	0	0	0	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								
Serum ferritin decreased[1, †]								
Number of participants affected	0	0	0	0	0	0	0	3
Number of events								
Number of participants at risk [blank=Total]								

	Metabolism and nutrition disorders							
Hyperuricaemia[1, †]								
Number of participants affected	2	1	0	0	3	0	6	6
Number of events								
Number of participants at risk [blank=Total]								
Hypertriglyceridaemia[1, †]								
Number of participants affected	1	1	0	0	0	0	8	6
Number of events								
Number of participants at risk [blank=Total]								
Diabetes mellitus[1, †]								
Number of participants affected	1	0	0	0	0	0	3	0
Number of events								
Number of participants at risk [blank=Total]								
Hypoalbuminaemia[1, †]								
Number of participants affected	1	0	0	0	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								
Increased appetite[1, †]								
Number of participants affected	0	0	0	1	1	0	0	2
Number of events								
Number of participants at risk [blank=Total]								
Hypophosphataemia[1, †]								
Number of participants affected	0	0	0	1	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								
Hypercholesterolaemia[1, †]								
Number of participants affected	0	0	0	0	0	0	6	10
Number of events								
Number of participants at risk [blank=Total]								
Hyperglycaemia[1, †]								
Number of participants affected	0	0	0	0	0	0	2	0
Number of events								

Number of participants at risk [blank=Total]								
Hypokalaemia[1, †]								
Number of participants affected	0	0	0	0	0	0	4	0
Number of events								
Number of participants at risk [blank=Total]								
Decreased appetite[1, †]								
Number of participants affected	0	0	0	0	0	0	0	3
Number of events								
Number of participants at risk [blank=Total]								
Iron deficiency[1, †]								
Number of participants affected	0	0	0	0	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								

	Musculoskeletal and connective tissue disorders							
Back pain[1, †]								
Number of participants affected	3	1	1	1	1	1	11	8
Number of events								
Number of participants at risk [blank=Total]								
Arthralgia[1, †]								
Number of participants affected	2	0	1	0	1	1	8	11
Number of events								
Number of participants at risk [blank=Total]								
Neck pain[1, †]								
Number of participants affected	1	1	0	0	0	0	2	2
Number of events								
Number of participants at risk [blank=Total]								
Joint stiffness[1, †]								
Number of participants affected	1	0	0	0	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								

Muscle spasms[1, †]								
Number of participants affected	0	1	0	1	1	1	5	4
Number of events								
Number of participants at risk [blank=Total]								
Musculoskeletal pain[1, †]								
Number of participants affected	1	0	0	1	1	1	4	4
Number of events								
Number of participants at risk [blank=Total]								
Myalgia[1, †]								
Number of participants affected	0	0	1	0	0	0	2	7
Number of events								
Number of participants at risk [blank=Total]								
Pain in extremity[1, †]								
Number of participants affected	0	0	0	1	4	1	6	11
Number of events								
Number of participants at risk [blank=Total]								
Bone pain[1, †]								
Number of participants affected	0	0	0	0	1	1	3	3
Number of events								
Number of participants at risk [blank=Total]								
Muscular weakness[1, †]								
Number of participants affected	0	0	0	1	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								
Osteoarthritis[1, †]								
Number of participants affected	0	0	0	0	0	0	3	3
Number of events								
Number of participants at risk [blank=Total]								
Intervertebral disc protrusion[1, †]								
Number of participants affected	0	0	0	0	0	0	0	3
Number of events								
Number of								

participants at risk [blank=Total]								
Osteoporosis[1, †]								
Number of participants affected	0	0	0	0	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								

	Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Basal cell carcinoma[1, †]								
Number of participants affected	0	0	0	0	0	0	0	4
Number of events								
Number of participants at risk [blank=Total]								
Squamous cell carcinoma of skin[1, †]								
Number of participants affected	0	0	0	0	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								
Uterine leiomyoma[1, †]								
Number of participants affected	0	0	0	0	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								

	Nervous system disorders							
Dizziness[1, †]								
Number of participants affected	2	1	1	0	3	0	6	5
Number of events								
Number of participants at risk [blank=Total]								
Headache[1, †]								
Number of participants affected	2	0	1	0	6	2	4	10
Number of events								
Number of participants at risk [blank=Total]								
Dysgeusia[1, †]								
Number of participants affected	1	0	0	0	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								

Neuropathy peripheral[1, †]								
Number of participants affected	1	0	0	0	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								
Perineurial cyst[1, †]								
Number of participants affected	1	0	0	0	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								
Peripheral sensory neuropathy[1, †]								
Number of participants affected	0	1	0	0	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								
Post herpetic neuralgia[1, †]								
Number of participants affected	0	1	0	0	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								
Restless legs syndrome[1, †]								
Number of participants affected	1	0	0	0	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								
Paraesthesia[1, †]								
Number of participants affected	0	0	0	0	0	1	2	2
Number of events								
Number of participants at risk [blank=Total]								
Peripheral sensorimotor neuropathy[1, †]								
Number of participants affected	0	0	0	0	0	1	0	0
Number of events								
Number of participants at risk [blank=Total]								
Memory impairment[1, †]								
Number of participants affected	0	0	0	0	0	0	2	2
Number of events								
Number of								

participants at risk [blank=Total]								
Trigeminal neuralgia[1, †]								
Number of participants affected	0	0	0	0	0	0	2	0
Number of events								
Number of participants at risk [blank=Total]								
Dysaesthesia[1, †]								
Number of participants affected	0	0	0	0	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								
Hypoaesthesia[1, †]								
Number of participants affected	0	0	0	0	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								
Presyncope[1, †]								
Number of participants affected	0	0	0	0	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								
Tremor[1, †]								
Number of participants affected	0	0	0	0	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								

	Psychiatric disorders							
Insomnia[1, †]								
Number of participants affected	1	0	2	0	1	1	5	4
Number of events								
Number of participants at risk [blank=Total]								
Anxiety[1, †]								
Number of participants affected	0	0	0	0	0	0	0	4
Number of events								
Number of participants at risk [blank=Total]								
Depression[1, †]								

Number of participants affected	0	0	0	0	0	0	0	3
Number of events								
Number of participants at risk [blank=Total]								

	Renal and urinary disorders							
Dysuria[1, †]								
Number of participants affected	0	0	0	0	0	0	2	2
Number of events								
Number of participants at risk [blank=Total]								
Nephrolithiasis[1, †]								
Number of participants affected	0	0	0	0	0	0	0	3
Number of events								
Number of participants at risk [blank=Total]								

	Reproductive system and breast disorders							
Benign prostatic hyperplasia[1, †]								
Number of participants affected	0	0	0	0	0	0	2	0
Number of events								
Number of participants at risk [blank=Total]								
Amenorrhoea[1, †]								
Number of participants affected	0	0	0	0	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								
Menstruation irregular[1, †]								
Number of participants affected	0	0	0	0	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								

	Respiratory, thoracic and mediastinal disorders							
Cough[1, †]								
Number of participants affected	2	1	1	0	4	1	12	12
Number of events								
Number of participants at risk [blank=Total]								
Dyspnoea[1, †]								

Number of participants affected	2	0	1	0	1	1	4	4
Number of events								
Number of participants at risk [blank=Total]								
Oropharyngeal pain[1, †]								
Number of participants affected	0	1	2	0	1	1	3	3
Number of events								
Number of participants at risk [blank=Total]								
Dyspnoea exertional[1, †]								
Number of participants affected	0	0	1	0	0	0	2	2
Number of events								
Number of participants at risk [blank=Total]								
Rhinorrhoea[1, †]								
Number of participants affected	0	0	1	0	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								
Sleep apnoea syndrome[1, †]								
Number of participants affected	0	0	1	0	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								
Epistaxis[1, †]								
Number of participants affected	0	0	0	0	0	0	0	3
Number of events								
Number of participants at risk [blank=Total]								

	Skin and subcutaneous tissue disorders							
Pruritus[1, †]								
Number of participants affected	2	0	0	0	2	0	5	4
Number of events								
Number of participants at risk [blank=Total]								
Erythema nodosum[1, †]								
Number of participants affected	0	1	0	0	0	0	0	0
Number of events								
Number of								

participants at risk [blank=Total]								
Mucocutaneous rash[1, †]								
Number of participants affected	1	0	0	0	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								
Rash pruritic[1, †]								
Number of participants affected	0	1	0	0	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								
Skin lesion[1, †]								
Number of participants affected	0	0	1	0	1	1	6	6
Number of events								
Number of participants at risk [blank=Total]								
Urticaria[1, †]								
Number of participants affected	0	0	1	0	0	0	0	0
Number of events								
Number of participants at risk [blank=Total]								
Actinic keratosis[1, †]								
Number of participants affected	0	0	0	0	0	0	4	2
Number of events								
Number of participants at risk [blank=Total]								
Ecchymosis[1, †]								
Number of participants affected	0	0	0	0	0	0	2	2
Number of events								
Number of participants at risk [blank=Total]								
Night sweats[1, †]								
Number of participants affected	0	0	0	0	0	0	5	2
Number of events								
Number of participants at risk [blank=Total]								
Skin ulcer[1, †]								
Number of participants affected	0	0	0	0	0	0	2	0

Number of events								
Number of participants at risk [blank=Total]								
Hyperhidrosis[1, †]								
Number of participants affected	0	0	0	0	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								
Rash[1, †]								
Number of participants affected	0	0	0	0	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								

	Surgical and medical procedures							
Cataract operation[1, †]								
Number of participants affected	0	0	0	0	0	0	2	0
Number of events								
Number of participants at risk [blank=Total]								
Tooth extraction[1, †]								
Number of participants affected	0	0	0	0	0	0	0	2
Number of events								
Number of participants at risk [blank=Total]								

	Vascular disorders							
Hypertension[1, †]								
Number of participants affected	1	0	0	2	0	0	5	8
Number of events								
Number of participants at risk [blank=Total]								
Hot flush[1, †]								
Number of participants affected	0	0	0	1	0	1	0	2
Number of events								
Number of participants at risk [blank=Total]								
Hypertensive crisis[1, †]								
Number of participants affected	0	0	0	0	0	1	0	0
Number of events								
Number of								

participants at risk [blank=Total]								
Venous thrombosis limb[1, †]								
Number of participants affected	0	0	0	0	0	1	0	0
Number of events								
Number of participants at risk [blank=Total]								

†	Events were collected by systematic assessment
1	Term from vocabulary, *MedDRA (Unspecified)*