Protocol Registration Receipt
08/15/2013

Grantor: CDER IND/IDE Number: 65,747 Serial Number: 65,747

Pazopanib Versus Placebo in Patients With Soft Tissue Sarcoma Whose Disease Has Progressed During or Following Prior Therapy (PALETTE)

This study has been completed.

Sponsor:	GlaxoSmithKline
Collaborators:	
Information provided by (Responsible Party):	GlaxoSmithKline
ClinicalTrials.gov Identifier:	NCT00753688

Purpose

A randomized double blind phase III trial of Pazopanib versus placebo in patients with soft tissue sarcoma whose disease has progressed during or following prior therapy

Condition	Intervention	Phase
Sarcoma, Soft Tissue	Drug: PAZOPANIB	Phase 3

Condition	Intervention	Phase
	Drug: Placebo	

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor), Randomized, Safety/Efficacy Study
Official Title: A Randomized Double Blind Phase III Trial of Pazopanib Versus Placebo in Patients With Soft Tissue Sarcoma Whose Disease Has Progressed During or Following Prior Therapy

Further study details as provided by GlaxoSmithKline:

Primary Outcome Measure:

- Progression-free Survival (PFS) [Time Frame: From the date of randomization until the date of the first documented radiological progression or date of death from any cause, whichever came first (assessed for an average of 10 months)] [Designated as safety issue: No]

  PFS was defined as the time interval between the date of randomization and the earliest date of either disease progression or death due to any cause. The diagnosis of progression was based on tumor measurements, according to Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.0 criteria, by independent radiologic assessment. The Kaplan-Meier method was used for PFS estimates.

Secondary Outcome Measures:

- Overall Survival (OS) [Time Frame: From the date of randomization until 215 deaths (assessed for an average of 12 months)] [Designated as safety issue: No]

  OS was defined as the time from the date of randomization to the date of death due to any cause. The length of this interval was calculated as the date of death minus the date of randomization plus 1 day. Participants who were alive at the time of analysis were censored at the date of last follow-up. The interim OS analysis was conducted when 215 (77 percent [%]) of the 279 required death events had occurred in the study. The Kaplan-Meier method was used for OS estimates.
- Number of Participants in the Indicated Categories for Overall Response Assessed by an Independent Radiologist and the Investigator [Time Frame: From the start of treatment until disease progression (assessed for an average of 10 months)] [Designated as safety issue: No]

  Overall response is defined as the number of participants who had a complete response (CR) or a partial response (PR). According to RECIST, Version 1.0: CR, disappearance of all lesions; PR, a >=30% decrease in the sum of the longest dimensions (LD) of the target lesions (TLs) taking as a reference the baseline sum LD; Progressive disease (PD), a >=20% increase in the sum of the LD of TLs, or the appearance of >=1 new lesion; Stable Disease (SD), neither PR nor PD, persistence of >=1 non-TL. Participants with no follow-up radiological disease assessment were categorized as not evaluable (NE).
- Time to Response Assessed by an Independent Radiologist and the Investigator [Time Frame: From the date of randomization until the date of the first documented evidence of CR or PR (assessed for an average of 10 months)] [Designated as safety issue: No]

  Time to response was defined as the time from the date of randomization until the date of first documented evidence of CR or PR (whichever status was recorded first). The Kaplan-Meier method was used for time to response estimates.

- Duration of Response Assessed by the Independent Radiologist and the Investigator [Time Frame: From the date of randomization until the date of the first documented evidence of CR or PR (assessed for an average of 10 months)] [Designated as safety issue: No]

  Duration of response was defined as the time from the date of the first documented evidence of CR or PR until the date of either the first documented sign of PD or death due to any cause. Participants who neither died nor progressed were censored at the date of the last adequate radiologic assessment. The Kaplan-Meier method was used for duration of response estimates.
- PFS in the Indicated Histology Subgroups of Soft Tissue Sarcoma (STS) [Time Frame: From the date of randomization until the date of the first documented progression or the date of death from any cause, whichever came first (assessed for an average of 10 months)] [Designated as safety issue: No]

  PFS was defined as the time interval between the date of randomization and the earliest date of either disease progression or death due to any cause. Participants were analyzed for PFS in histology subgroups of STS (as per the World Health Organization [WHO] classification, 2008): leiomyosarcoma (malignant cancer of smooth muscle), synovial sarcoma (cancer near the joints of the arm or leg), and other STS (without the tumor type of leiomyosarcoma or synovial sarcoma), based on independent review.The Kaplan-Meier method was used for PFS estimates.
- Change From Baseline in Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) [Time Frame: Baseline, Day 8, Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, 64, 68, 72, 76, 80, 88, 96, and 104] [Designated as safety issue: No]

  Change from baseline in on-therapy SBP and DBP was calculated as the values at the indicated time points (Day 8 and Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, 64, 68, 72, 76, 80, 88, 96, and 104) minus the value at baseline.
- Change From Baseline in Heart Rate [Time Frame: Baseline, Day 8, Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, 64, 68, 72, 76, 80, 88, 96, and 104] [Designated as safety issue: No]

  Change from baseline in on-therapy heart rate was calculated as the value at the indicated time points (Day 8 and Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, 64, 68, 72, 76, 80, 88, 96, and 104) minus the value at baseline.
- Number of Participants With the Indicated Grade Shifts From Baseline Grade for Hemoglobin Level, Lymphocyte Count, White Blood Cell Count, Neutrophil Count, and Platelet Count [Time Frame: From baseline (Day 1) until study drug discontinuation or end of treatment (assessed for an average of 20 weeks)] [Designated as safety issue: No]

  Shifts in hematology values by grade were summarized based on the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE Version 3.0). Grade refers to the severity of the AE. The CTCAE Version 3.0 displays Grades 1 through 5 with unique clinical descriptions of severity for each AE based on this general guideline. Participants with a missing baseline grade were assumed to have a baseline Grade of 0. Any increase in grade from baseline and shifts to Grade 3 (severe AE) and 4 (life-threatening or disabling AE) at any point in the study after baseline are reported.
- Number of Participants With the Indicated Grade Shifts From Baseline Grade for Alkaline Phosphatase, Alanine Aminotransferase, Aspartate Aminotransferase, Albumin, Creatinine, Hyper/Hypoglycemia, Hyper/Hypokalemia, Hyper/Hyponatremia, and Total Bilirubin [Time Frame: From baseline (Day 1) until study drug discontinuation or end of treatment (assessed for an average of 20 weeks)] [Designated as safety issue: No]

  Shifts in clinical chemistry values by grade were summarized based on the NCI CTCAE Version 3.0. Participants with a missing baseline grade were assumed to have a baseline Grade of 0. Any increase in grade from baseline and shifts to Grade 3 and 4 at any point in the study after baseline are reported. alkaline phosphatase, ALKP; alanine aminotransferase, ALT; aspartate aminotransferase, AST. Hyper/hypoglycemia refers to high/low glucose; hyper/hypokalemia refers to high/low potassium; hyper/hyponatremia refers to high/low sodium.

- Number of Participants With the Indicated Absolute Percent Change From Baseline (BL) in Left Ventricular Ejection Fraction (LVEF) at Any Time Post-BL (Worst Case On-therapy) [Time Frame: Baseline (within 14 days of the first dose of study drug) and any time post-baseline until study drug discontinuation or end of treatment (assessed for an average of 20 weeks)] [Designated as safety issue: No]

  LVEF is the measurement of how much blood is being pumped out of the left ventricle of the heart (the main pumping chamber) with each contraction and is used to determine cardiac function (based on the institutional lower limit of normal [LLN]). LVEF was assessed at BL, Week 12, and every second scheduled visit thereafter until study drug discontinuation and end of treatment or as clinically indicated by using multi-gated acquisition scan (MUGA) or echocardiogram (ECHO). Absolute change from BL was calculated as the on-study value minus the baseline value (LVEF is calculated as a percentage).

Enrollment: 369
Study Start Date: October 2008
Study Completion Date: December 2012
Primary Completion Date: November 2010

Arms	Assigned Interventions
Placebo Comparator: PLACEBO matching placebo 800 mg once daily orally	Drug: Placebo matching placebo 800 mg once daily orally
Experimental: PAZOPANIB 800 mg once daily orally	Drug: PAZOPANIB 800 mg once daily orally

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both

Inclusion/Exclusion Criteria:

- High or intermediate grade of soft tissue sarcoma; Low grade tumours allowed provided there is disease progression.
- Metastatic and measurable disease (RECIST);
- Subjects can have received maximum of 4 prior lines of systemic therapies (including up to 2 combination regimens) for advanced disease. (Neo) adjuvant/maintenance treatments are not counted for this criterion;
- Last dose of prior therapy can be given upto 14 days prior to start of study if all ongoing toxicity from prior anticancer therapy are grade 1 or resolved (except alopecia).

- Must have failed anthracycline-based therapy and available standard chemotherapies at the treating institution except if medically contraindicated or refused by patient;
- No treatment with anti-angiogenesis inhibitors;
- Age > 18 years
- WHO PS 0-1;
- No leptomeningeal or brain metastases, normal bone marrow, liver, renal and cardiac functions;
- No prior history of malignancies other than sarcoma (except for basal cell or squamous cell carcinoma of the skin or carcinoma in-situ of the cervix or breast or the patient has been free of any other malignancies for > 3 years)
- Adequate bone marrow function; adequate blood clotting results; adequate hepatic and renal function;
- No poorly controlled hypertension;
- Clinically normal cardiac function;
- No clinically significant gastrointestinal abnormalities including malabsorption syndrome, major resection of the stomach or small bowel that could affect the absorption of study drug, active peptic ulcer disease, inflammatory bowel disease, ulcerative colitis, or other gastrointestinal conditions with increased risk of perforation, history of abdominal fistula, gastrointestinal perforation, or intra-abdominal abscess within 28 days prior to beginning study treatment.
- No cerebrovascular accidents 1
- No transient ischemic attack, deep vein thrombosis or pulmonary embolism within past six months;
- No active bleeding or bleeding diathesis;
- No hemoptysis within six weeks of study drug;
- No major surgery or trauma within 28 days of therapy treatment;
- Concomitant medication restriction;
- No known immediate or delayed hypersensitivity reaction or idiosyncrasy to drugs chemically related to pazopanib
- Ability to swallow & retain oral medication
- Adequate contraception must be used;
- No Psychological familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be assessed with the patient before randomization in the trial.

Contacts and Locations

Locations

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Investigators

Study Director:	GSK Clinical Trials	GlaxoSmithKline

More Information

Publications:

van Der Graaf WTA, Blay JY, Chawla SP, Kim D, Nguyen BB, Casali PG. Schöffski P, Aglietta M, Staddon AP, Beppu Y, Le Cesnen A, Gelderblom H, Judson IR, Araki N, Ouali M, Marreaud S, Hodge R, Dewji R, Demetri G, AP Dei Tos, Hohenberger P. Pazopanib in metastatic soft tissue sarcoma (PALETTE, EORTC 62072): a randomized, double-blind, placebo controlled phase 3 trial.. Lancet. 2012;379(9829):1879-86.

Responsible Party:	GlaxoSmithKline
Study ID Numbers:	VEG110727
Health Authority:	United States: Food and Drug Administration

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Study Results

Participant Flow

Reporting Groups

	Description
Placebo	Matching placebo tablets administered orally once daily for a duration

	Description
	until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent
Pazopanib	Pazopanib 200 milligrams (mg) and 400 mg film-coated tablets (containing pazopanib monohydrochloride) administered orally at a dose of 800 mg once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent

Overall Study

	Placebo	Pazopanib
Started	123	246
Ongoing - in Follow-up	15	31
Completed	0	0
Not Completed	123	246
Death	102	203
Missing	4	9
Participant Withdrew Consent	2	2
Ongoing - in Follow-up	15	31
Adverse Event	0	1

Baseline Characteristics

Reporting Groups

	Description
Placebo	Matching placebo tablets administered orally once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent
Pazopanib	Pazopanib 200 milligrams (mg) and 400 mg film-coated tablets (containing pazopanib monohydrochloride) administered orally at a dose of 800 mg once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent

Baseline Measures

	Placebo	Pazopanib	Total
Number of Participants	123	246	369
Age, Continuous [units: Years] Mean (Standard Deviation)	51.7 (13.77)	54.0 (14.92)	53.2 (14.57)
Gender, Male/Female [units: Participants]			
Female	69	147	216
Male	54	99	153
Race/Ethnicity, Customized [units: participants]			
African American/African Heritage	2	4	6
American Indian or Alaska Native	0	1	1
Asian - Central/South Asian Heritage	2	0	2

	Placebo	Pazopanib	Total
Asian - East Asian Heritage	7	24	31
Asian - Japanese Heritage	16	31	47
Asian - South East Asian Heritage	2	2	4
White - Arabic/North African Heritage	2	1	3
White - White/Caucasian/European Heritage	89	174	263
Mixed Race	1	0	1
Unknown	2	9	11
Study-Specific Measure [1] [units: participants]			
Leiomyosarcoma	49	109	158
Synovial sarcoma	13	25	38
Other STS histologies	61	112	173

[1] Participants were categorized in the following histology subgroups of STS (as per the World Health Organization [WHO] classification, 2008): leiomyosarcoma, defined as malignant cancer of smooth muscle; synovial sarcoma, defined as cancer near the joints of the arm or leg; and other STS, defined as sarcoma without the tumor type of leiomyosarcoma or synovial sarcoma.

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Progression-free Survival (PFS)

Measure Description	PFS was defined as the time interval between the date of randomization and the earliest date of either disease progression or death due to any cause. The diagnosis of progression was based on tumor measurements, according to Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.0 criteria, by independent radiologic assessment. The Kaplan-Meier method was used for PFS estimates.
Time Frame	From the date of randomization until the date of the first documented radiological progression or date of death from any cause, whichever came first (assessed for an average of 10 months)
Safety Issue?	No

Analysis Population Description

Intent-to-Treat (ITT) Population: all randomized participants analyzed in the treatment arm they were allocated by randomization.

Reporting Groups

	Description
Placebo	Matching placebo tablets administered orally once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent
Pazopanib	Pazopanib 200 milligrams (mg) and 400 mg film-coated tablets (containing pazopanib monohydrochloride) administered orally at a dose of 800 mg once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent

Measured Values

	Placebo	Pazopanib
Number of Participants Analyzed	123	246
Progression-free Survival (PFS)	7.0 (4.4 to	20.0 (17.9 to

	Placebo	Pazopanib
[units: weeks] Median (95% Confidence Interval)	8.1)	21.3)

Statistical Analysis 1 for Progression-free Survival (PFS)

Groups	Placebo, Pazopanib
Method	Log Rank
P-Value	<0.001
Hazard Ratio (HR)	0.35
95% Confidence Interval	0.26 to 0.48

Additional details about the analysis, such as null hypothesis and power calculation:

[Not specified.]

Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

Stratified two-sided log rank p-value

Other relevant information, such as adjustments or degrees of freedom:

[Not specified.]

Other relevant estimation information:

The HR was adjusted for World Health Organization (WHO) performance status scale (0 versus 1 at Baseline) and number of prior lines of systemic treatment for advanced disease (0/1 versus 2+).

2. Secondary Outcome Measure:

Measure Title	Overall Survival (OS)
Measure Description	OS was defined as the time from the date of randomization to the date of death due to any cause. The length of this interval was calculated as the date of death minus the date of randomization plus 1 day.

	Participants who were alive at the time of analysis were censored at the date of last follow-up. The interim OS analysis was conducted when 215 (77 percent [%]) of the 279 required death events had occurred in the study. The Kaplan-Meier method was used for OS estimates.
Time Frame	From the date of randomization until 215 deaths (assessed for an average of 12 months)
Safety Issue?	No

Analysis Population Description

ITT Population

Reporting Groups

	Description
Placebo	Matching placebo tablets administered orally once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent
Pazopanib	Pazopanib 200 milligrams (mg) and 400 mg film-coated tablets (containing pazopanib monohydrochloride) administered orally at a dose of 800 mg once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent

Measured Values

	Placebo	Pazopanib
Number of Participants Analyzed	123	246
Overall Survival (OS) [units: months] Median (95% Confidence Interval)	10.7 (9.0 to 13.1)	12.6 (10.9 to 14.9)

Statistical Analysis 1 for Overall Survival (OS)

Groups	Placebo, Pazopanib
Method	Log Rank
P-Value	0.256
Hazard Ratio (HR)	0.86
95% Confidence Interval	0.67 to 1.12

Additional details about the analysis, such as null hypothesis and power calculation:

[Not specified.]

Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

Stratified two-sided log rank p-value

Other relevant information, such as adjustments or degrees of freedom:

[Not specified.]

Other relevant estimation information:

The HR was adjusted for World Health Organization (WHO) performance status scale (0 versus 1 at Baseline) and number of prior lines of systemic treatment for advanced disease (0/1 versus 2+).

3. Secondary Outcome Measure:

Measure Title	Number of Participants in the Indicated Categories for Overall Response Assessed by an Independent Radiologist and the Investigator
Measure Description	Overall response is defined as the number of participants who had a complete response (CR) or a partial response (PR). According to RECIST, Version 1.0: CR, disappearance of all lesions; PR, a >=30% decrease in the sum of the longest dimensions (LD) of the target lesions (TLs) taking as a reference the baseline sum LD; Progressive disease (PD), a >=20% increase in the sum of the LD of TLs, or the

	appearance of >=1 new lesion; Stable Disease (SD), neither PR nor PD, persistence of >=1 non-TL. Participants with no follow-up radiological disease assessment were categorized as not evaluable (NE).
Time Frame	From the start of treatment until disease progression (assessed for an average of 10 months)
Safety Issue?	No

Analysis Population Description

ITT Population

Reporting Groups

	Description
Placebo	Matching placebo tablets administered orally once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent
Pazopanib	Pazopanib 200 milligrams (mg) and 400 mg film-coated tablets (containing pazopanib monohydrochloride) administered orally at a dose of 800 mg once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent

Measured Values

	Placebo	Pazopanib
Number of Participants Analyzed	123	246
Number of Participants in the Indicated Categories for Overall Response Assessed by an Independent Radiologist and the Investigator		

	Placebo	Pazopanib
[units: participants]		
CR, Independent radiologist assessed	0	0
PR, Independent radiologist assessed	0	11
SD, Independent radiologist assessed	33	134
PD, Independent radiologist assessed	76	66
NE, Independent radiologist assessed	14	35
CR, Investigator assessed	0	0
PR, Investigator assessed	0	23
SD, Investigator assessed	36	138
PD, Investigator assessed	83	70
NE, Investigator assessed	4	15

4. Secondary Outcome Measure:

Measure Title	Time to Response Assessed by an Independent Radiologist and the Investigator
Measure Description	Time to response was defined as the time from the date of randomization until the date of first documented evidence of CR or PR (whichever status was recorded first). The Kaplan-Meier method was used for time to response estimates.
Time Frame	From the date of randomization until the date of the first documented evidence of CR or PR (assessed for an average of 10 months)
Safety Issue?	No

Analysis Population Description

ITT Population. Only participants who achieved a confirmed CR or PR, as determined independently by the Independent Radiologist and the Investigator, were analyzed. Only results for the pazopanib arm are given because there was no response in the placebo arm.

Reporting Groups

	Description
Placebo	Matching placebo tablets administered orally once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent
Pazopanib	Pazopanib 200 milligrams (mg) and 400 mg film-coated tablets (containing pazopanib monohydrochloride) administered orally at a dose of 800 mg once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent

Measured Values

	Placebo	Pazopanib
Number of Participants Analyzed	0	23
Time to Response Assessed by an Independent Radiologist and the Investigator [units: weeks] Median (95% Confidence Interval)		
Independent radiologist assessed, n=0, 11		8.4 (4.7 to 19.1)
Investigator assessed, n=0, 23		8.1 (4.6 to 11.7)

5. Secondary Outcome Measure:

Measure Title	Duration of Response Assessed by the Independent Radiologist and the Investigator
Measure Description	Duration of response was defined as the time from the date of the first documented evidence of CR or PR until the date of either the first documented sign of PD or death due to any cause. Participants who neither died nor progressed were censored at the date of the last adequate radiologic assessment. The Kaplan-Meier method was used for duration of response estimates.
Time Frame	From the date of randomization until the date of the first documented evidence of CR or PR (assessed for an average of 10 months)
Safety Issue?	No

Analysis Population Description

ITT Population. Only participants who achieved a confirmed CR or PR, as determined independently by the Independent Radiologist and the Investigator, were analyzed. Only results for the pazopanib arm are given because there was no response in the placebo arm.

Reporting Groups

	Description
Placebo	Matching placebo tablets administered orally once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent
Pazopanib	Pazopanib 200 milligrams (mg) and 400 mg film-coated tablets (containing pazopanib monohydrochloride) administered orally at a dose of 800 mg once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent

Measured Values

	Placebo	Pazopanib
Number of Participants Analyzed	0	23
Duration of Response Assessed by the Independent Radiologist and the Investigator [units: weeks] Median (95% Confidence Interval)		
Independent radiologist assessed, n=0, 11		38.9 (16.7 to 40.0)
Investigator assessed, n=0, 23		32.1 (22.6 to 44.0)

6. Secondary Outcome Measure:

Measure Title	PFS in the Indicated Histology Subgroups of Soft Tissue Sarcoma (STS)
Measure Description	PFS was defined as the time interval between the date of randomization and the earliest date of either disease progression or death due to any cause. Participants were analyzed for PFS in histology subgroups of STS (as per the World Health Organization [WHO] classification, 2008): leiomyosarcoma (malignant cancer of smooth muscle), synovial sarcoma (cancer near the joints of the arm or leg), and other STS (without the tumor type of leiomyosarcoma or synovial sarcoma), based on independent review.The Kaplan-Meier method was used for PFS estimates.
Time Frame	From the date of randomization until the date of the first documented progression or the date of death from any cause, whichever came first (assessed for an average of 10 months)
Safety Issue?	No

Analysis Population Description

ITT Population. The "n"s in the category titles represent the number of participants in each treatment arm with the indicated STS.

Reporting Groups

	Description
Placebo	Matching placebo tablets administered orally once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent
Pazopanib	Pazopanib 200 milligrams (mg) and 400 mg film-coated tablets (containing pazopanib monohydrochloride) administered orally at a dose of 800 mg once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent

Measured Values

	Placebo	Pazopanib
Number of Participants Analyzed	123	246
PFS in the Indicated Histology Subgroups of Soft Tissue Sarcoma (STS) [units: weeks] Median (95% Confidence Interval)		
Leiomyosarcoma, n=49, 109	8.1 (7.6 to 9.3)	20.1 (13.3 to 23.1)
Synovial sarcoma, n=13, 25	4.1 (3.7 to 8.9)	17.9 (8.9 to 27.1)
Other STS, n=61, 112	4.3 (4.0 to 7.9)	20.1 (13.0 to 27.1)

Statistical Analysis 1 for PFS in the Indicated Histology Subgroups of Soft Tissue Sarcoma (STS)

Groups	Placebo, Pazopanib
Method	Log Rank
P-Value	<0.001
Hazard Ratio (HR)	0.37
95% Confidence Interval	0.23 to 0.60

Additional details about the analysis, such as null hypothesis and power calculation:

[Not specified.]

Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

Stratified two-sided log rank p-value for leiomyosarcoma

Other relevant information, such as adjustments or degrees of freedom:

[Not specified.]

Other relevant estimation information:

The HR was adjusted for World Health Organization (WHO) performance status scale (0 versus 1 at Baseline) and number of prior lines of systemic treatment for advanced disease (0/1 versus 2+).

Statistical Analysis 2 for PFS in the Indicated Histology Subgroups of Soft Tissue Sarcoma (STS)

Groups	Placebo, Pazopanib
Method	Log Rank
P-Value	0.005
Hazard Ratio (HR)	0.43
95% Confidence Interval	0.19 to 0.98

Additional details about the analysis, such as null hypothesis and power calculation:

[Not specified.]

Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for

statistical significance:

Stratified two-sided log rank p-value for synovial sarcoma

Other relevant information, such as adjustments or degrees of freedom:

[Not specified.]

Other relevant estimation information:

The HR was adjusted for World Health Organization (WHO) performance status scale (0 versus 1 at Baseline) and number of prior lines of systemic treatment for advanced disease (0/1 versus 2+).

Statistical Analysis 3 for PFS in the Indicated Histology Subgroups of Soft Tissue Sarcoma (STS)

Groups	Placebo, Pazopanib
Method	Log Rank
P-Value	<0.001
Hazard Ratio (HR)	0.39
95% Confidence Interval	0.25 to 0.60

Additional details about the analysis, such as null hypothesis and power calculation:

[Not specified.]

Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

Stratified two-sided log rank p-value for other STS histologies

Other relevant information, such as adjustments or degrees of freedom:

[Not specified.]

Other relevant estimation information:

The HR was adjusted for World Health Organization (WHO) performance status scale (0 versus 1 at Baseline) and number of prior lines of systemic treatment for advanced disease (0/1 versus 2+).

7. Secondary Outcome Measure:

Measure Title	Change From Baseline in Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP)
Measure Description	Change from baseline in on-therapy SBP and DBP was calculated as the values at the indicated time points (Day 8 and Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, 64, 68, 72, 76, 80, 88, 96, and 104) minus the value at baseline.
Time Frame	Baseline, Day 8, Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, 64, 68, 72, 76, 80, 88, 96, and 104
Safety Issue?	No

Analysis Population Description

Safety Population: all participants who had started their allocated treatment (at least one dose of the study drug). Data were analyzed for participants who were on-therapy and provided data at the indicated time point.

Reporting Groups

	Description
Placebo	Matching placebo tablets administered orally once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent
Pazopanib	Pazopanib 200 milligrams (mg) and 400 mg film-coated tablets (containing pazopanib monohydrochloride) administered orally at a dose of 800 mg once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent

Measured Values

	Placebo	Pazopanib
Number of Participants Analyzed	120	235

	Placebo	Pazopanib
Change From Baseline in Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) [units: Millimeters of mercury] Mean (Standard Deviation)		
SBP, Day 8, n=120, 235	-0.6 (13.37)	10.3 (15.96)
SBP, Week 4, n=106, 224	-0.2 (12.83)	10.9 (19.47)
SBP, Week 8, n=71, 180	0.0 (13.60)	7.2 (17.46)
SBP, Week 12, n=31, 115	-3.1 (15.82)	4.9 (18.21)
SBP, Week 16, n=35, 136	-0.6 (15.91)	4.9 (18.49)
SBP, Week 20, n=14, 66	-2.6 (14.89)	3.9 (19.84)
SBP, Week 24, n=22, 107	-3.8 (16.71)	2.7 (20.24)
SBP, Week 28, n=9, 41	0.2 (22.82)	0.9 (15.70)
SBP, Week 32, n=12, 76	2.8 (12.50)	3.2 (18.89)
SBP, Week 36, n=5, 24	3.6 (10.71)	1.9 (17.71)
SBP, Week 40, n=5, 62	6.8 (15.47)	3.2 (19.75)
SBP, Week 44, n=3, 16	6.0 (19.31)	1.2 (19.45)
SBP, Week 48, n=3, 37	-1.7 (14.05)	-1.7 (16.90)
SBP, Week 52, n=1, 6	-4.0 (0)	9.8 (18.28)
SBP, Week 56, n=1, 27	16.0 (0)	1.4 (20.86)
SBP, Week 60, n=0, 6	0 (0)	7.0 (18.60)
SBP, Week 64, n=1, 15	20.0 (0)	-3.0 (19.26)
SBP, Week 68, n=0, 2	0 (0)	14.5 (3.54)

	Placebo	Pazopanib
SBP, Week 72, n=1, 9	8.0 (0)	-1.1 (15.83)
SBP, Week 76, n=0, 1	0 (0)	16.0 (0)
SBP, Week 80, n=1, 5	19.0 (0)	-0.9 (22.66)
SBP, Week 88, n=1, 3	3.0 (0)	3.9 (22.90)
SBP, Week 96, n=1, 2	13.0 (0)	-3.0 (14.14)
SBP, Week 104, n=1, 1	18.0 (0)	6.0 (0)
DBP, Day 8, n=120, 235	-0.2 (9.53)	7.2 (10.68)
DBP, Week 4, n=106, 224	-0.2 (9.51)	8.2 (11.37)
DBP, Week 8, n=71, 180	-0.3 (9.24)	6.6 (12.18)
DBP, Week 12, n=31, 115	-0.1 (10.81)	3.9 (11.31)
DBP, Week 16, n=35, 136	0.8 (10.46)	5.3 (12.12)
DBP, Week 20, n=14, 66	-0.3 (8.61)	4.5 (12.22)
DBP, Week 24, n=22, 107	-1.6 (11.78)	3.7 (14.44)
DBP, Week 28, n=9, 41	-1.9 (12.33)	3.7 (11.28)
DBP, Week 32, n=12, 76	-2.0 (7.30)	3.9 (11.59)
DBP, Week 36, n=5, 24	-6.6 (9.63)	4.1 (13.28)
DBP, Week 40, n=5, 62	3.4 (9.24)	2.9 (13.34)
DBP, Week 44, n=3, 16	4.7 (5.03)	1.7 (12.48)
DBP, Week 48, n=3, 37	2.0 (4.36)	3.7 (12.01)
DBP, Week 52, n=1, 6	1.0 (0)	12.0 (15.06)
DBP, Week 56, n=1, 27	12.0 (0)	4.4 (12.28)

	Placebo	Pazopanib
DBP, Week 60, n=0, 6	0 (0)	12.7 (14.39)
DBP, Week 64, n=1, 15	10.0 (0)	-2.2 (14.21)
DBP, Week 68, n=0, 2	0 (0)	17.0 (25.46)
DBP, Week 72, n=1, 9	13.0 (0)	0.8 (12.88)
DBP, Week 76, n=0, 1	0 (0)	4.0 (0)
DBP, Week 80, n=1, 5	14.0 (0)	-3.3 (15.15)
DBP, Week 88, n=1, 3	9.0 (0)	5.2 (3.87)
DBP, Week 96, n=1, 2	6.0 (0)	7.0 (5.66)
DBP, Week 104, n=1, 1	12.0 (0)	12.0 (0)

8. Secondary Outcome Measure:

Measure Title	Change From Baseline in Heart Rate
Measure Description	Change from baseline in on-therapy heart rate was calculated as the value at the indicated time points (Day 8 and Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, 64, 68, 72, 76, 80, 88, 96, and 104) minus the value at baseline.
Time Frame	Baseline, Day 8, Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, 64, 68, 72, 76, 80, 88, 96, and 104
Safety Issue?	No

Analysis Population Description

Safety Population. Data were analyzed for participants who were on-therapy and provided data at the indicated time point.

Reporting Groups

	Description
Placebo	Matching placebo tablets administered orally once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent
Pazopanib	Pazopanib 200 milligrams (mg) and 400 mg film-coated tablets (containing pazopanib monohydrochloride) administered orally at a dose of 800 mg once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent

Measured Values

	Placebo	Pazopanib
Number of Participants Analyzed	113	225
Change From Baseline in Heart Rate [units: beats per minute] Mean (Standard Deviation)		
Day 8, n=113, 225	1.6 (12.61)	-4.4 (11.24)
Week 4, n=98, 208	3.1 (13.06)	-2.7 (13.51)
Week 8, n=66, 171	2.1 (15.03)	-1.6 (14.31)
Week 12, n=29, 103	1.1 (17.32)	-2.4 (11.67)
Week 16, n=31, 127	6.0 (16.78)	-3.7 (12.76)
Week 20, n=12, 57	0.6 (22.95)	-3.4 (11.71)
Week 24, n=21, 94	4.5 (18.14)	-5.0 (12.83)
Week 28, n=7, 37	-1.1 (27.99)	-3.8 (13.68)
Week 32, n=12, 72	-1.7 (18.38)	-2.7 (12.63)
Week 36, n=5, 24	-11.8 (32.57)	0.9 (13.37)

	Placebo	Pazopanib
Week 40, n=5, 58	-8.2 (30.19)	-2.4 (12.84)
Week 44, n=3, 15	7.0 (16.09)	-0.9 (14.02)
Week 48, n=3, 33	9.0 (18.00)	1.9 (14.38)
Week 52, n=1, 5	-8.0 (0)	-3.4 (16.96)
Week 56, n=1, 24	31.0 (0)	-0.4 (15.14)
Week 60, n=0, 6	0 (0)	4.3 (15.13)
Week 64, n=1, 13	36.0 (0)	-1.5 (13.56)
Week 68, n=0, 2	0 (0)	9.5 (0.71)
Week 72, n=1, 8	14.0 (0)	2.6 (12.60)
Week 76, n=0, 1	0 (0)	5.0 (0)
Week 80, n=1, 5	24.0 (0)	2.8 (16.08)
Week 88, n=1, 3	9.0 (0)	-3.0 (10.58)
Week 96, n=1, 2	17.0 (0)	-5.0 (4.24)
Week 104, n=1, 1	30.0 (0)	1.0 (0)

9. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Grade Shifts From Baseline Grade for Hemoglobin Level, Lymphocyte Count, White Blood Cell Count, Neutrophil Count, and Platelet Count
Measure Description	Shifts in hematology values by grade were summarized based on the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE Version 3.0). Grade refers to the severity of

	the AE. The CTCAE Version 3.0 displays Grades 1 through 5 with unique clinical descriptions of severity for each AE based on this general guideline. Participants with a missing baseline grade were assumed to have a baseline Grade of 0. Any increase in grade from baseline and shifts to Grade 3 (severe AE) and 4 (life-threatening or disabling AE) at any point in the study after baseline are reported.
Time Frame	From baseline (Day 1) until study drug discontinuation or end of treatment (assessed for an average of 20 weeks)
Safety Issue?	No

Analysis Population Description

Safety Population. Data were analyzed for participants who were on-therapy and provided data at the indicated time point.

Reporting Groups

	Description
Placebo	Matching placebo tablets administered orally once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent
Pazopanib	Pazopanib 200 milligrams (mg) and 400 mg film-coated tablets (containing pazopanib monohydrochloride) administered orally at a dose of 800 mg once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent

Measured Values

	Placebo	Pazopanib
Number of Participants Analyzed	123	239
Number of Participants With the Indicated Grade Shifts From Baseline Grade for		

	Placebo	Pazopanib
Hemoglobin Level, Lymphocyte Count, White Blood Cell Count, Neutrophil Count, and Platelet Count [units: participants]		
Hemoglobin, Any Increase, n=123, 239	28	65
Hemoglobin, Increase to Grade 3, n=123, 239	1	11
Hemoglobin, Increase to Grade 4, n=123, 239	1	4
Lymphocytes, Any Increase, n=123, 238	44	102
Lymphocytes, Increase to Grade 3, n=123, 238	11	23
Lymphocytes, Increase to Grade 4, n=123, 238	2	0
Neutrophils, Any Increase, n=123, 239	8	79
Neutrophils, Increase to Grade 3, n=123, 239	0	10
Neutrophils, Increase to Grade 4, n=123, 239	0	0
Platelets, Any Increase, n=123, 239	7	86
Platelets, Increase to Grade 3, n=123, 239	0	7
Platelets, Increase to Grade 4, n=123, 239	0	2
White Blood Cells, Any Increase,	18	106

	Placebo	Pazopanib
n=123, 239		
White Blood Cells, Increase to Grade 3, n=123, 239	0	3
White Blood Cells, Increase to Grade , n=123, 239	0	0

10. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Grade Shifts From Baseline Grade for Alkaline Phosphatase, Alanine Aminotransferase, Aspartate Aminotransferase, Albumin, Creatinine, Hyper/Hypoglycemia, Hyper/Hypokalemia, Hyper/Hyponatremia, and Total Bilirubin
Measure Description	Shifts in clinical chemistry values by grade were summarized based on the NCI CTCAE Version 3.0. Participants with a missing baseline grade were assumed to have a baseline Grade of 0. Any increase in grade from baseline and shifts to Grade 3 and 4 at any point in the study after baseline are reported. alkaline phosphatase, ALKP; alanine aminotransferase, ALT; aspartate aminotransferase, AST. Hyper/hypoglycemia refers to high/low glucose; hyper/hypokalemia refers to high/low potassium; hyper/hyponatremia refers to high/low sodium.
Time Frame	From baseline (Day 1) until study drug discontinuation or end of treatment (assessed for an average of 20 weeks)
Safety Issue?	No

Analysis Population Description

Safety Population. Data were analyzed for participants who were on-therapy and provided data at the indicated time point.

Reporting Groups

	Description
Placebo	Matching placebo tablets administered orally once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent
Pazopanib	Pazopanib 200 milligrams (mg) and 400 mg film-coated tablets (containing pazopanib monohydrochloride) administered orally at a dose of 800 mg once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent

Measured Values

	Placebo	Pazopanib
Number of Participants Analyzed	123	239
Number of Participants With the Indicated Grade Shifts From Baseline Grade for Alkaline Phosphatase, Alanine Aminotransferase, Aspartate Aminotransferase, Albumin, Creatinine, Hyper/Hypoglycemia, Hyper/Hypokalemia, Hyper/Hyponatremia, and Total Bilirubin [units: participants]		
ALKP, Any Increase, n=123, 237	28	77
ALKP, Increase to Grade 3, n=123, 237	1	7
ALKP, Increase to Grade 4, n=123, 237	0	0
ALT, Any Increase, n=123, 237	22	110
ALT, Increase to Grade 3, n=123, 237	3	18
ALT, Increase to Grade 4, n=123, 237	1	5

	Placebo	Pazopanib
AST, Any Increase, n=123, 239	27	122
AST, Increase to Grade 3, n=123, 239	2	13
AST, Increase to Grade 4, n=123, 239	0	6
Albumin, Any Increase, n=123, 239	26	81
Albumin, Increase to Grade 3, n=123, 239	0	2
Albumin, Increase to Grade 4, n=123, 239	0	0
Creatinine, Any Increase, n=123, 239	9	28
Creatinine, Increase to Grade 3, n=123, 239	0	1
Creatinine, Increase to Grade 4, n=123, 239	0	0
Hyperglycemia, Any Increase, n=122, 238	43	106
Hyperglycemia, Increase to Grade 3, n=122, 238	2	1
Hyperglycemia, Increase to Grade 4, n=122, 238	0	0
Hyperkalemia, Any Increase, n=123, 238	13	37
Hyperkalemia, Increase to Grade 3, n=123, 238	0	3
Hyperkalemia, Increase to Grade 4, n=123, 238	0	0

	Placebo	Pazopanib
Hypernatremia, Any Increase, n=123, 238	3	10
Hypernatremia, Increase to Grade 3, n=123, 238	0	0
Hypernatremia, Increase to Grade 4, n=123, 238	0	0
Hypoglycemia, Any Increase, n=122, 238	4	21
Hypoglycemia, Increase to Grade 3, n=122, 238	0	1
Hypoglycemia, Increase to Grade 4, n=122, 238	0	0
Hypokalemia, Any Increase, n=123, 238	11	32
Hypokalemia, Increase to Grade 3, n=123, 238	1	6
Hypokalemia, Increase to Grade 4, n=123, 238	0	1
Hyponatremia, Any Increase, n=123, 238	25	74
Hyponatremia, Increase to Grade 3, n=123, 238	4	9
Hyponatremia, Increase to Grade 4, n=123, 238	0	0
Total Bilirubin, Any Increase, n=122, 237	9	68
Total Bilirubin, Increase to Grade 3,	2	3

	Placebo	Pazopanib
n=122, 237		
Total Bilirubin, Increase to Grade 4, n=122, 237	0	0

11. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Absolute Percent Change From Baseline (BL) in Left Ventricular Ejection Fraction (LVEF) at Any Time Post-BL (Worst Case On-therapy)
Measure Description	LVEF is the measurement of how much blood is being pumped out of the left ventricle of the heart (the main pumping chamber) with each contraction and is used to determine cardiac function (based on the institutional lower limit of normal [LLN]). LVEF was assessed at BL, Week 12, and every second scheduled visit thereafter until study drug discontinuation and end of treatment or as clinically indicated by using multi-gated acquisition scan (MUGA) or echocardiogram (ECHO). Absolute change from BL was calculated as the on-study value minus the baseline value (LVEF is calculated as a percentage).
Time Frame	Baseline (within 14 days of the first dose of study drug) and any time post-baseline until study drug discontinuation or end of treatment (assessed for an average of 20 weeks)
Safety Issue?	No

Analysis Population Description

Safety Population. Data were analyzed for participants who were on-therapy and provided data at the indicated time point.

Reporting Groups

	Description
Placebo	Matching placebo tablets administered orally once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent
Pazopanib	Pazopanib 200 milligrams (mg) and 400 mg film-coated tablets (containing pazopanib monohydrochloride) administered orally at a dose of 800 mg once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent

Measured Values

	Placebo	Pazopanib
Number of Participants Analyzed	39	140
Number of Participants With the Indicated Absolute Percent Change From Baseline (BL) in Left Ventricular Ejection Fraction (LVEF) at Any Time Post-BL (Worst Case On-therapy) [units: participants]		
Any Increase	15	39
No Change	6	14
0 to <10% Decrease	15	66
10 to 19% Decrease	3	15
>=20% Decrease	0	6
>=10% Decrease and >= LLN	3	8
>=10% Decrease and below LLN	0	13
>=20% Decrease and >= LLN	0	1

	Placebo	Pazopanib
>=20% Decrease and below LLN	0	5

Reported Adverse Events

Reporting Groups

	Description
Placebo	Matching placebo tablets administered orally once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent
Pazopanib	Pazopanib 200 milligrams (mg) and 400 mg film-coated tablets (containing pazopanib monohydrochloride) administered orally at a dose of 800 mg once daily for a duration until participants experienced disease progression, death, unacceptable toxicity, or participants withdrew consent

Time Frame

Serious adverse events (SAEs) and non-serious AEs were collected from Baseline through End of Study (average of 20 study weeks).

Additional Description

The Safety Population, comprised of all participants who had started their allocated treatment (at least one dose of the study drug), was used for all safety analyses.

Serious Adverse Events

	Placebo	Pazopanib
Total # participants affected/at risk	29/123 (23.58%)	99/240 (41.25%)

	Placebo	Pazopanib
Blood and lymphatic system disorders		
Febrile neutropenia †[A]		
# participants affected/at risk	0/123 (0%)	2/240 (0.83%)
# events		
Thrombotic microangiopathy †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Cardiac disorders		
Atrial fibrillation †[A]		
# participants affected/at risk	1/123 (0.81%)	1/240 (0.42%)
# events		
Atrial flutter †[A]		
# participants affected/at risk	1/123 (0.81%)	0/240 (0%)
# events		
Cardio-respiratory arrest †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		

	Placebo	Pazopanib
Left ventricular dysfunction †[A]		
# participants affected/at risk	0/123 (0%)	5/240 (2.08%)
# events		
Myocardial infarction †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Pericardial effusion †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Sinus bradycardia †[A]		
# participants affected/at risk	1/123 (0.81%)	0/240 (0%)
# events		
Gastrointestinal disorders		
Colonic obstruction †[A]		
# participants affected/at risk	1/123 (0.81%)	1/240 (0.42%)
# events		
Constipation †[A]		

	Placebo	Pazopanib
# participants affected/at risk	1/123 (0.81%)	0/240 (0%)
# events		
Diarrhea † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Duodenal ulcer † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Enterocutaneous fistula † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Gastric stenosis † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Gastrointestinal fistula † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Gastrointestinal pain † [A]		

	Placebo	Pazopanib
# participants affected/at risk	2/123 (1.63%)	4/240 (1.67%)
# events		
Hematemesis †[A]		
# participants affected/at risk	1/123 (0.81%)	0/240 (0%)
# events		
Ileus †[A]		
# participants affected/at risk	1/123 (0.81%)	0/240 (0%)
# events		
Nausea †[A]		
# participants affected/at risk	1/123 (0.81%)	1/240 (0.42%)
# events		
Oesophageal haemorrhage †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Oesophageal haemorrhage †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)

	Placebo	Pazopanib
# events		
Oesophageal stenosis † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Oesophageal stenosis † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Peritoneal hemorrhage † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Small intestinal obstruction † [A]		
# participants affected/at risk	0/123 (0%)	2/240 (0.83%)
# events		
Upper gastrointestinal hemorrhage † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Vomiting † [A]		

	Placebo	Pazopanib
# participants affected/at risk	1/123 (0.81%)	4/240 (1.67%)
# events		
General disorders		
Asthenia † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Chest pain † [A]		
# participants affected/at risk	0/123 (0%)	4/240 (1.67%)
# events		
Death † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Disease progression † [A]		
# participants affected/at risk	1/123 (0.81%)	1/240 (0.42%)
# events		
Fatigue † [A]		
# participants affected/at risk	1/123 (0.81%)	5/240 (2.08%)

	Placebo	Pazopanib
# events		
Localized edema †[A]		
# participants affected/at risk	1/123 (0.81%)	0/240 (0%)
# events		
Mass †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Mass †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Multi-organ failure †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Performance status decreased †[A]		
# participants affected/at risk	0/123 (0%)	3/240 (1.25%)
# events		
Pyrexia †[A]		
# participants affected/at	3/123 (2.44%)	1/240 (0.42%)

	Placebo	Pazopanib
risk		
# events		
Immune system disorders		
Hypersensitivity † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Infections and infestations		
Abscess † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Bacterial sepsis † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Bacterial sepsis † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Biliary tract infection † [A]		

	Placebo	Pazopanib
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Candida sepsis † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Clostridial infection † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Cystitis † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Device related infection † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Diverticulitis † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Gastroenteritis † [A]		

	Placebo	Pazopanib
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Infection † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Infective tenosynovitis † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Lactobacillus infection † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Lung infection † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Pelvic abscess † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Pneumonia † [A]		

	Placebo	Pazopanib
# participants affected/at risk	0/123 (0%)	4/240 (1.67%)
# events		
Pyelonephritis † [A]		
# participants affected/at risk	1/123 (0.81%)	0/240 (0%)
# events		
Sepsis † [A]		
# participants affected/at risk	1/123 (0.81%)	2/240 (0.83%)
# events		
Skin infection † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Streptococcal sepsis † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Superinfection bacterial † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Tooth abscess † [A]		

	Placebo	Pazopanib
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Wound infection †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Wound infection pseudomonas †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Injury, poisoning and procedural complications		
Femur fracture †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Radiation injury †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Radiation skin injury †[A]		
# participants affected/at	0/123 (0%)	1/240 (0.42%)

	Placebo	Pazopanib
risk		
# events		
Vascular graft thrombosis † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Investigations		
Alanine aminotransferase † [A]		
# participants affected/at risk	1/123 (0.81%)	1/240 (0.42%)
# events		
Alanine aminotransferase increased † [A]		
# participants affected/at risk	1/123 (0.81%)	9/240 (3.75%)
# events		
Aspartate aminotransferase † [A]		
# participants affected/at risk	0/123 (0%)	2/240 (0.83%)
# events		
Aspartate aminotransferase increased † [A]		

	Placebo	Pazopanib
# participants affected/at risk	0/123 (0%)	6/240 (2.5%)
# events		
Bilirubin conjugated †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Blood alkaline phosphatase increased †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Blood bilirubin increased †[A]		
# participants affected/at risk	1/123 (0.81%)	2/240 (0.83%)
# events		
Blood cholesterol abnormal †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Blood lactate dehydrogenase increased †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)

	Placebo	Pazopanib
# events		
Blood potassium decreased † [A]		
# participants affected/at risk	1/123 (0.81%)	1/240 (0.42%)
# events		
Gamma-glutamyltransferase increased † [A]		
# participants affected/at risk	0/123 (0%)	6/240 (2.5%)
# events		
Hemoglobin † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Hemoglobin decreased † [A]		
# participants affected/at risk	2/123 (1.63%)	8/240 (3.33%)
# events		
Lymphocyte percentage † [A]		
# participants affected/at risk	2/123 (1.63%)	0/240 (0%)
# events		
Neutrophil count decreased		

	Placebo	Pazopanib
† [A]		
# participants affected/at risk	0/123 (0%)	2/240 (0.83%)
# events		
Neutrophil percentage † [A]		
# participants affected/at risk	1/123 (0.81%)	2/240 (0.83%)
# events		
Neutrophil percentage decreased † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Platelet count decreased † [A]		
# participants affected/at risk	1/123 (0.81%)	3/240 (1.25%)
# events		
Urine protein/creatinine ratio † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
White blood cell count decreased † [A]		

	Placebo	Pazopanib
# participants affected/at risk	0/123 (0%)	2/240 (0.83%)
# events		
Metabolism and nutrition disorders		
Decreased appetite †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Dehydration †[A]		
# participants affected/at risk	0/123 (0%)	2/240 (0.83%)
# events		
Hypercalcemia †[A]		
# participants affected/at risk	1/123 (0.81%)	1/240 (0.42%)
# events		
Hypoglycemia †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Lactic acidosis †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)

	Placebo	Pazopanib
# events		
Musculoskeletal and connective tissue disorders		
Musculoskeletal chest pain †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Musculoskeletal pain †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Myalgia †[A]		
# participants affected/at risk	1/123 (0.81%)	2/240 (0.83%)
# events		
Rhabdomyolysis †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Tendonitis †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)

	Placebo	Pazopanib
# events		
Tendonitis † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Leiomyosarcoma metastatic † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Malignant pleural effusion † [A]		
# participants affected/at risk	1/123 (0.81%)	2/240 (0.83%)
# events		
Metastases to skin † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Neoplasm † [A]		

	Placebo	Pazopanib
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Tumor pain †[A]		
# participants affected/at risk	3/123 (2.44%)	4/240 (1.67%)
# events		
Nervous system disorders		
Cerebral infarction †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Headache †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Hemorrhage intracranial †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Peripheral motor neuropathy †[A]		
# participants affected/at	1/123 (0.81%)	0/240 (0%)

	Placebo	Pazopanib
risk		
# events		
Peripheral sensory neuropathy †[A]		
# participants affected/at risk	1/123 (0.81%)	1/240 (0.42%)
# events		
Subarachnoid hemorrhage †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Syncope †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Psychiatric disorders		
Confusional state †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Depressed mood †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)

	Placebo	Pazopanib
# events		
Renal and urinary disorders		
Hematuria †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Nephrolithiasis †[A]		
# participants affected/at risk	1/123 (0.81%)	0/240 (0%)
# events		
Nephrotic syndrome †[A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Renal failure †[A]		
# participants affected/at risk	0/123 (0%)	2/240 (0.83%)
# events		
Respiratory, thoracic and mediastinal disorders		
Acute respiratory distress syndrome †[A]		

	Placebo	Pazopanib
# participants affected/at risk	1/123 (0.81%)	0/240 (0%)
# events		
Dyspnea †[A]		
# participants affected/at risk	3/123 (2.44%)	9/240 (3.75%)
# events		
Hemoptysis †[A]		
# participants affected/at risk	1/123 (0.81%)	0/240 (0%)
# events		
Lung disorder †[A]		
# participants affected/at risk	0/123 (0%)	2/240 (0.83%)
# events		
Pleural effusion †[A]		
# participants affected/at risk	1/123 (0.81%)	4/240 (1.67%)
# events		
Pneumothorax †[A]		
# participants affected/at risk	0/123 (0%)	6/240 (2.5%)
# events		
Pulmonary hemorrhage †[A]		

	Placebo	Pazopanib
# participants affected/at risk	1/123 (0.81%)	0/240 (0%)
# events		
Respiratory failure † [A]		
# participants affected/at risk	2/123 (1.63%)	0/240 (0%)
# events		
Skin and subcutaneous tissue disorders		
Skin ulcer † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Vascular disorders		
Embolism arterial † [A]		
# participants affected/at risk	2/123 (1.63%)	6/240 (2.5%)
# events		
Hemorrhage † [A]		
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		
Ischemia † [A]		

	Placebo	Pazopanib
# participants affected/at risk	0/123 (0%)	1/240 (0.42%)
# events		

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA

Other Adverse Events

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

	Placebo	Pazopanib
Total # participants affected/at risk	108/123 (87.8%)	232/240 (96.67%)
Cardiac disorders		
Left ventricular dysfunction †[A]		
# participants affected/at risk	5/123 (4.07%)	19/240 (7.92%)
# events		
Endocrine disorders		
Hypothyroidism †[A]		
# participants affected/at risk	0/123 (0%)	20/240 (8.33%)
# events		
Eye disorders		
Vision blurred †[A]		
# participants affected/at	2/123 (1.63%)	12/240 (5%)

	Placebo	Pazopanib
risk		
# events		
Gastrointestinal disorders		
Abdominal pain upper †[A]		
# participants affected/at risk	7/123 (5.69%)	19/240 (7.92%)
# events		
Constipation †[A]		
# participants affected/at risk	21/123 (17.07%)	39/240 (16.25%)
# events		
Diarrhea †[A]		
# participants affected/at risk	19/123 (15.45%)	141/240 (58.75%)
# events		
Dry mouth †[A]		
# participants affected/at risk	6/123 (4.88%)	16/240 (6.67%)
# events		
Dyspepsia †[A]		
# participants affected/at risk	2/123 (1.63%)	18/240 (7.5%)

	Placebo	Pazopanib
# events		
Gastrointestinal pain †[A]		
# participants affected/at risk	11/123 (8.94%)	57/240 (23.75%)
# events		
Nausea †[A]		
# participants affected/at risk	27/123 (21.95%)	135/240 (56.25%)
# events		
Stomatitis †[A]		
# participants affected/at risk	4/123 (3.25%)	27/240 (11.25%)
# events		
Vomiting †[A]		
# participants affected/at risk	14/123 (11.38%)	81/240 (33.75%)
# events		
General disorders		
Chest pain †[A]		
# participants affected/at risk	7/123 (5.69%)	26/240 (10.83%)
# events		
Chills †[A]		

	Placebo	Pazopanib
# participants affected/at risk	1/123 (0.81%)	14/240 (5.83%)
# events		
Edema peripheral † [A]		
# participants affected/at risk	11/123 (8.94%)	33/240 (13.75%)
# events		
Fatigue † [A]		
# participants affected/at risk	59/123 (47.97%)	157/240 (65.42%)
# events		
Pyrexia † [A]		
# participants affected/at risk	12/123 (9.76%)	25/240 (10.42%)
# events		
Infections and infestations		
Nasopharyngitis † [A]		
# participants affected/at risk	7/123 (5.69%)	13/240 (5.42%)
# events		
Investigations		
Ear, nose and throat examination abnormal † [A]		

	Placebo	Pazopanib
# participants affected/at risk	3/123 (2.44%)	29/240 (12.08%)
# events		
Weight decreased † [A]		
# participants affected/at risk	9/123 (7.32%)	122/240 (50.83%)
# events		
Weight increased † [A]		
# participants affected/at risk	9/123 (7.32%)	12/240 (5%)
# events		
Metabolism and nutrition disorders		
Decreased appetite † [A]		
# participants affected/at risk	23/123 (18.7%)	97/240 (40.42%)
# events		
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain † [A]		
# participants affected/at risk	24/123 (19.51%)	56/240 (23.33%)
# events		

	Placebo	Pazopanib
Myalgia †[A]		
# participants affected/at risk	11/123 (8.94%)	56/240 (23.33%)
# events		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Tumour pain †[A]		
# participants affected/at risk	26/123 (21.14%)	71/240 (29.58%)
# events		
Nervous system disorders		
Dizziness †[A]		
# participants affected/at risk	5/123 (4.07%)	26/240 (10.83%)
# events		
Dysgeusia †[A]		
# participants affected/at risk	4/123 (3.25%)	66/240 (27.5%)
# events		
Headache †[A]		
# participants affected/at	10/123	57/240

	Placebo	Pazopanib
risk	(8.13%)	(23.75%)
# events		
Peripheral sensory neuropathy † [A]		
# participants affected/at risk	10/123 (8.13%)	22/240 (9.17%)
# events		
Psychiatric disorders		
Anxiety † [A]		
# participants affected/at risk	8/123 (6.5%)	20/240 (8.33%)
# events		
Insomnia † [A]		
# participants affected/at risk	7/123 (5.69%)	24/240 (10%)
# events		
Respiratory, thoracic and mediastinal disorders		
Cough † [A]		
# participants affected/at risk	15/123 (12.2%)	43/240 (17.92%)
# events		
Dysphonia † [A]		

	Placebo	Pazopanib
# participants affected/at risk	3/123 (2.44%)	18/240 (7.5%)
# events		
Dyspnea † [A]		
# participants affected/at risk	21/123 (17.07%)	49/240 (20.42%)
# events		
Epistaxis † [A]		
# participants affected/at risk	2/123 (1.63%)	19/240 (7.92%)
# events		
Skin and subcutaneous tissue disorders		
Alopecia † [A]		
# participants affected/at risk	1/123 (0.81%)	29/240 (12.08%)
# events		
Dry skin † [A]		
# participants affected/at risk	1/123 (0.81%)	16/240 (6.67%)
# events		
Exfoliative rash † [A]		
# participants affected/at risk	11/123 (8.94%)	46/240 (19.17%)

	Placebo	Pazopanib
# events		
Hair color changes † [A]		
# participants affected/at risk	3/123 (2.44%)	93/240 (38.75%)
# events		
Skin disorder † [A]		
# participants affected/at risk	1/123 (0.81%)	28/240 (11.67%)
# events		
Skin hypopigmentation † [A]		
# participants affected/at risk	0/123 (0%)	28/240 (11.67%)
# events		
Vascular disorders		
Hypertension † [A]		
# participants affected/at risk	7/123 (5.69%)	101/240 (42.08%)
# events		

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA

More Information

Certain Agreements:

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

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

GSK agreements may vary with individual investigators, but will not prohibit any investigator from publishing. GSK supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

Limitations and Caveats:

Results Point of Contact:

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