ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 08/30/2013

A Study of Androgen Deprivation With Leuprolide, +/- Docetaxel for Clinically Asymptomatic Prostate Cancer Participants With a Rising Prostate Specific Antigen (PSA) (Rising PSA)

This study has been terminated.
(Company decision to discontinue the study, not due to any safety or efficacy concerns)

Sponsor:	Sanofi
Collaborators:	
Information provided by (Responsible Party):	Sanofi
ClinicalTrials.gov Identifier:	NCT00514917

Purpose

The primary objective was to evaluate and compare the efficacy of androgen deprivation with or without docetaxel as determined by the median progression free survival (PFS) over the period of 18-month therapy and at least 18-month follow-up.

The secondary objectives were:

- To assess cancer specific survival;
- To compare overall survival between the 2 treatment groups;
- To evaluate patient-reported outcomes including quality of life, fatigue, and sexual functioning as measured by 3 different assessments.

Condition	Intervention	Phase
Prostatic Neoplasms	Drug: Docetaxel Drug: Leuprolide Drug: Bicalutamide	Phase 3

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Open Label, Randomized, Efficacy Study

Official Title: A Randomized, Open Label, Multicenter, Phase III, 2-Arm Study of Androgen Deprivation With Leuprolide, +/- Docetaxel for Clinically Asymptomatic Prostate Cancer Subjects With a Rising PSA Following Definitive Local Therapy

Further study details as provided by Sanofi:

Primary Outcome Measure:

- Median Progression-Free Survival (PFS) in Intent-to-treat (ITT) Population [Time Frame: Randomization until PSA progression or radiographic progression or death due to prostate cancer, assessed up to Month 60] [Designated as safety issue: No]
  PFS was the time from randomization to the date of first documented prostate specific antigen (PSA) progression, or radiographic progression, or death due to prostate cancer in the absence of previous documentation of disease progression, whichever occurred first. PSA progression was determined as: a) During treatment period: a 50 percent (%) increase from baseline, which was confirmed by a second value; b) During follow-up: detectable PSA (defined as PSA greater than or equal to 0.05 nanogram per millimeter [ng/mL]), which was confirmed by consecutive observation (not less than 2 weeks apart). Median PFS was estimated using the Kaplan-Meier method.
- Progression-Free Survival (PFS) Rate at Month 36 in ITT Population [Time Frame: Month 36] [Designated as safety issue: No]
  PFS rate at Month 36 was defined as probability of being progression-free at Month 36. PFS rate was estimated using the Kaplan-Meier method.
- Median Progression-Free Survival (PFS) in Testosterone Specific Evaluable Population [Time Frame: Randomization until PSA progression or radiographic progression or death due to prostate cancer, assessed up to Month 60] [Designated as safety issue: No]
  PFS was the time from randomization to the date of first documented PSA progression, or radiographic progression, or death due to prostate cancer in the absence of previous documentation of disease progression, whichever occurred first. Median PFS was estimated using the Kaplan-Meier method.
- Progression-Free Survival (PFS) Rate at Month 36 in Testosterone Specific Evaluable Population [Time Frame: Month 36] [Designated as safety issue: No]
  PFS rate at Month 36 was defined as probability of being progression-free at Month 36. PFS rate was estimated using the Kaplan-Meier method.

Secondary Outcome Measures:

- Overall Survival (OS): Number of Participants Who Died (All Cause) [Time Frame: Randomization until death due to any cause, assessed up to Month 60] [Designated as safety issue: No]
  The OS was the time interval from the date of randomization to the date of death due to any cause. OS was to be analyzed using the Kaplan-Meier method. However, the analysis was not performed due to insufficient number of events. Reported is the number of participants who died from any cause.
- Cancer-Specific Survival: Number of Participants Who Died (Cancer-Specific) [Time Frame: Randomization until death due to prostate cancer, assessed up to Month 60] [Designated as safety issue: No]
  The cancer-specific survival was the time from the date of randomization to the date of death due to prostate cancer. Cancer-specific survival was to be analyzed using the Kaplan-Meier method. However, the analysis was not performed due to insufficient number of events. Reported is the number of participants who died from prostate cancer.
- Change From Baseline in Functional Assessment of Cancer Therapy-Prostate (FACT-P) Total Score at End of Treatment (EOT) [Time Frame: Baseline, EOT (up to Month 18)] [Designated as safety issue: No]
  FACT-P is a 39-item participant questionnaire which assesses physical well-being (7 items), social/family well-being (7 items), emotional well-being (6 items), functional well-being (7 items), and additional prostate cancer specific concerns (12 items). All items are scored from 0 (not at all) to 4 (very much). The total FACT-P score ranges from 0-156, with higher scores representing a better quality of life with fewer symptoms. A score of 156 represents the best outcome.
- Change From Baseline in Functional Assessment of Cancer Therapy-Prostate (FACT-P) Trial Outcome Index (TOI) Score at EOT [Time Frame: Baseline, EOT (up to Month 18)] [Designated as safety issue: No]
  Physical well-being, functional well-being, and prostate cancer concerns sub-scales of the FACT-P questionnaire were combined to calculate TOI. Total TOI score ranges from 0 to 104, with higher scores representing a better quality of life with fewer symptoms.
- Change From Baseline in Multidimensional Assessment of Fatigue (MAF) Index Score at EOT [Time Frame: Baseline, EOT (up to Month 18)] [Designated as safety issue: No]

MAF scale consists of 16-items to measure 4 dimensions of fatigue during past week: severity (Item 1-2), distress (Item 3), degree of interference in activities of daily living (Item 4-14), and timing (Item 15-16). Item 1-14 are scored on a numeric rating scale from 1 to 10, where higher score indicate more severity/distress/interference. Item 15-16 had multiple choice responses (4 responses each). Scale Index was calculated using Item 1-15, in following steps: 1) Item 15 score converted to 1-10 scale by multiplying the score with 2.5; 2) Average score was calculated from Item 4-14; 3) Finally scale index was calculated by adding Items 1, 2, 3 scores with average score from step 2 and converted score of Item 15 from step 1. Total MAF scale index score ranges 1 (no fatigue) to 50 (severe fatigue).

- Change From Baseline in Erectile Function Domain of International Index of Erectile Function (EF-IIEF) Total Score at EOT [Time Frame: Baseline, EOT (up to Month 18)] [Designated as safety issue: No]

  EF-IIEF is a 6-item erectile function domain of IIEF. It consists of Question 1, 2, 3, 4, 5, and 15 of IIEF questionnaire. 5 questions are scored from 0 (no activity) to 5 (very high activity) and 1 question is scored from 1 (very low activity) to 5 (very high activity). Total EF-IIEF score ranges from 1 to 30, where higher score indicates high activity.

Other Pre-specified Outcome Measures:

- Number of Participants With Treatment-Emergent Adverse Events (TEAEs) [Time Frame: From first administration of study treatment until 30 days after the last administration of study treatment] [Designated as safety issue: Yes]

  TEAE: any adverse event (AE) that occurred or worsened during the on-treatment period, which was the period from first administration of study treatment until 30 days after last administration of study treatment. AE: any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. Serious AE: an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/ incapacity; congenital anomaly, or medically important. Drug-related AEs were any untoward medical occurrences attributed to study drug in a participant who received study drug. National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 3.0 Grade 3 (severe) and Grade 4 (life threatening/disabling) TEAEs were also reported.

Enrollment: 413
Study Start Date: July 2007
Primary Completion Date: September 2012
Study Completion Date: September 2012

Arms	Assigned Interventions
Experimental: Docetaxel+Leuprolide +Bicalutamide Participants received docetaxel 75 milligram per square meter (mg/m^2) intravenous infusion over 1 hour every 3 weeks up to 10 cycles (3 week cycle) along with leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.	Drug: Docetaxel 75 mg/m^2 intravenous infusion over 1 hour every 3 weeks up to 10 cycles. Other Names: TAXOTERE® XRP6976 Drug: Leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months. Other Names: Eligard® Drug: Bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.

Arms	Assigned Interventions
Active Comparator: Leuprolide+Bicalutamide Participants received leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.	Drug: Leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months. Other Names: Eligard® Drug: Bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.

Detailed Description:

The duration of the study per participant was to be at least 36 months, of which the treatment period was 18 months for all participants, followed by at least 18 months follow-up period.

Participants received study treatment for up to 18 months from the time of study therapy initiation or less if one of the following occurred: disease progression, unacceptable toxicity, death, participant refusal or treatment delay beyond the time frame that is permitted for each treatment.

Eligibility

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

Criteria

Inclusion Criteria:

- Diagnosis of prostate adenocarcinoma pathologically confirmed
- History of radical prostatectomy (pre-operative radiation therapy to the prostate or pelvis or salvage radiation after radical prostatectomy was allowed)
- Demonstration of biochemical progression of disease based on prostate specific antigen (PSA) doubling time. The minimum PSA value for eligibility was greater than or equal to (>=) 1. PSA doubling time over three values must be equal to (=) 9 months with a minimum of 3 weeks between assessments
- Serum testosterone >=100 nanogram per deciliter (ng/dL)
- Karnofsky performance status (KPS) >=70 percent (%)
- Adequate organ function as defined by the following laboratory criteria:
    - White blood cells >=3500 per cubic millimeter (mm^3)
    - Absolute neutrophil count (ANC) >=1500 per mm^3
    - Platelet count >=100,000 per mm^3
    - Hemoglobin >= 10.0 gram per deciliter (g/dL)
    - Total Bilirubin less than or equal to (<=) upper limit of normal (ULN) unless due to Gilbert's disease
    - Creatinine l <= 1.5 milligram per deciliter (mg/dL) or creatinine clearance >=60 cubic centimeters per minute
    - Aspartate transaminase (AST), alanine transaminase (ALT) and alkaline phosphatase within pre-defined ranges
- Previous hormonal therapy was allowed provided that the total duration of therapy did not exceed 6 months
- Man of childbearing potential who was willing to consent to use effective contraception while on treatment and for at least 3 months thereafter

- Participant who was willing and was able to comply with scheduled visits, treatment plans, laboratory tests, and other study procedures

Exclusion Criteria:

- Clinically significant cardiac disease (New York Heart Association Class III/IV), or severe debilitating pulmonary disease
- Uncontrolled serious active infection
- Anticipated duration of life < 2 years
- Less than 5-year history of successful treatment for other cancers or concurrent active nonprostate cancer other than nonmelanoma dermatologic tumor
- Peripheral neuropathy >=Grade 2
- History of hypersensitivity reaction to Docetaxel or other drugs formulated with polysorbate 80, leuprolide, or bicalutamide
- Prior chemotherapy within the past 10 years (except non-taxane based chemotherapy for treatment of other cancers); concurrent treatment on another clinical trial or with any other cancer therapy including chemotherapy, immunotherapy, radiotherapy (except salvage radiation therapy), chemoembolization therapy, cryotherapy
- Other severe acute or chronic medical conditions including psychiatric disease, or significant laboratory abnormality requiring further investigation that may cause undue risk for the participant's safety, delay or prohibit protocol participation, or interfere with the interpretation of study results, and in the judgment of the investigator would make the participant inappropriate for entry into this study
- Radiographic findings suspicious for metastatic disease in the treating physician's clinical judgment. Participant who had radiographically suspicious pelvic lymph nodes prior to radial prostatectomy, but who, at the time of enrollment did not have suspicious adenopathy was eligible. Participant was eligible even if he/she had tumor-containing pelvic adenopathy at the time of surgery as long as at the time of enrollment there was no radiographically evident nodal disease in the clinician's opinion
- Participant was the investigator or any sub-investigator, research assistant, pharmacist, study coordinator, other staff or relative thereof directly involved in the conduct of the protocol
- Participant unlikely to comply with protocol or research tests, for example, uncooperative attitude, inability to return for follow-up visits, and unlikelihood of completing the study
- Participant who participated in another clinical study/received investigational product within 30 days of screening

The above information was not intended to contain all considerations relevant to a participant's potential participation in a clinical trial.

Contacts and Locations

Locations

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Warsaw, Poland
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Bratislava, Slovakia
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Barcelona, Spain

Investigators

Study Director:	Barrett Childs, MD	sanofi-aventis

More Information

Responsible Party:	Sanofi
Study ID Numbers:	XRP6976J_3503 2007-000323-17 [EudraCT Number]
Health Authority:	United States: Institutional Review Board

Study Results

Participant Flow

Recruitment Details	Participants were enrolled from 53 sites in North America (the United States of America and Canada) and Europe. Study was terminated after all participants had completed treatment with docetaxel, but before all participants had completed 18 months follow-up. The termination was not due to any safety or efficacy concerns.

Reporting Groups

	Description
Docetaxel+Leuprolide+Bicalutamide	Participants received docetaxel 75 milligram per square meter (mg/m^2) intravenous infusion over 1 hour every 3 weeks up to 10 cycles (3 week cycle) along with leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.
Leuprolide+Bicalutamide	Participants received leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.

Overall Study

	Docetaxel+Leuprolide+Bicalutamide	Leuprolide+Bicalutamide
Started	207	206
Treated	196	204
Completed Study Treatment	170	182
Testosterone-Specific Evaluable	122	124
Completed	81	91
Not Completed	126	115
Death	4	10
Protocol Violation	1	0
Lost to Follow-up	4	3
Withdrawal by Subject	18	16
Discontinued due to study closure	88	81
Undefined	11	5

Baseline Characteristics

Analysis Population Description

Safety population included all randomized participants who received at least part of one dose of any of the study drugs.

Reporting Groups

	Description
Docetaxel+Leuprolide+Bicalutamide	Participants received docetaxel 75 milligram per square meter (mg/m^2) intravenous infusion over 1 hour every 3 weeks up to 10 cycles (3 week cycle) along with leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.
Leuprolide+Bicalutamide	Participants received leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.

Baseline Measures

	Docetaxel+Leuprolide+Bicalutamide	Leuprolide+Bicalutamide	Total
Number of Participants	196	204	400
Age, Continuous [units: years]	65.2 (6.97)	64.0 (6.97)	64.6 (6.99)

	Docetaxel+Leuprolide+Bicalutamide	Leuprolide+Bicalutamide	Total
Mean (Standard Deviation)			
Age, Customized [units: participants]			
Less Than (<) 65 Years	86	104	190
Greater Than or Equal to (>=) 65 to < 75 Years	95	89	184
>= 75 Years	15	11	26
Gender, Male/Female [units: participants]			
Female	0	0	0
Male	196	204	400
Race/Ethnicity, Customized [units: participants]			
Caucasian/White	175	184	359
Black	16	13	29
Asian/Oriental	1	0	1
Others	4	7	11
Body Surface Area (BSA) [1] [units: square meter (m^2)] Mean (Standard Deviation)	2.05 (0.176)	2.08 (0.194)	2.06 (0.186)
Prior Radiation Therapy [units: participants]	63	75	138

[1] BSA was calculated using the Dubois and Dubois formula: BSA (in square meter) = (weight^0.425* height^0.725)*0.007184; where weight is in kilogram (kg) and height is in centimeter (cm). Here “N” (number of participants analyzed) = 192, 198 for each treatment arm, respectively.

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Median Progression-Free Survival (PFS) in Intent-to-treat (ITT) Population

Measure Description	PFS was the time from randomization to the date of first documented prostate specific antigen (PSA) progression, or radiographic progression, or death due to prostate cancer in the absence of previous documentation of disease progression, whichever occurred first. PSA progression was determined as: a) During treatment period: a 50 percent (%) increase from baseline, which was confirmed by a second value; b) During follow-up: detectable PSA (defined as PSA greater than or equal to 0.05 nanogram per millimeter [ng/mL]), which was confirmed by consecutive observation (not less than 2 weeks apart). Median PFS was estimated using the Kaplan-Meier method.
Time Frame	Randomization until PSA progression or radiographic progression or death due to prostate cancer, assessed up to Month 60
Safety Issue?	No

Analysis Population Description

ITT population included all participants who were randomized, with study drug assignment designated according to randomization, regardless of whether participants received any study drug or a different drug from that to which they were randomized.

Reporting Groups

	Description
Docetaxel+Leuprolide+Bicalutamide	Participants received docetaxel 75 milligram per square meter (mg/m^2) intravenous infusion over 1 hour every 3 weeks up to 10 cycles (3 week cycle) along with leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.
Leuprolide+Bicalutamide	Participants received leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.

Measured Values

	Docetaxel+Leuprolide+Bicalutamide	Leuprolide+Bicalutamide
Number of Participants Analyzed	207	206
Median Progression-Free Survival (PFS) in Intent-to-treat (ITT) Population [units: months] Median (95% Confidence Interval)	25.4 (23.8 to 27.8)	23.3 (22.6 to 25.1)

Statistical Analysis 1 for Median Progression-Free Survival (PFS) in Intent-to-treat (ITT) Population

Statistical Analysis Overview	Comparison Groups	Docetaxel+Leuprolide+Bicalutamide, Leuprolide+Bicalutamide
	Comments	Null hypothesis: No difference between new treatment combination (Docetaxel+Leuprolide +Bicalutamide) and conventional treatment (Leuprolide+Bicalutamide). The study was sized to have 90% power to detect a difference between treatment arms at a 2-sided 0.05 significance level with 186 events and anticipating 10% non-evaluable participants.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0501
	Comments	A priori threshold for statistical significance = 0.05
	Method	Log Rank
	Comments	P-value was not adjusted for multiplicity of tests.

Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	1.29
	Confidence Interval	(2-Sided) 95% 1.00 to 1.65
	Estimation Comments	The hazard ratio Leuprolide+Bicalutamide vs. Docetaxel+Leuprolide+Bicalutamide was estimated using an un-stratified Cox proportional hazards model. A hazard ratio >1 indicates a lower risk of Docetaxel+Leuprolide, compared to Leuprolide.

2. Primary Outcome Measure:

Measure Title	Progression-Free Survival (PFS) Rate at Month 36 in ITT Population
Measure Description	PFS rate at Month 36 was defined as probability of being progression-free at Month 36. PFS rate was estimated using the Kaplan-Meier method.
Time Frame	Month 36
Safety Issue?	No

Analysis Population Description
ITT population.

Reporting Groups

	Description
Docetaxel+Leuprolide+Bicalutamide	Participants received docetaxel 75 milligram per square meter (mg/m^2) intravenous infusion over 1 hour every 3 weeks up to 10 cycles along with leuprolide 22.5 mg/m^2subcutaneous injection for every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.
Leuprolide+Bicalutamide	Participants received leuprolide 22.5 mg/m^2 subcutaneous injection for every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.

Measured Values

	Docetaxel+Leuprolide+Bicalutamide	Leuprolide+Bicalutamide
Number of Participants Analyzed	207	206
Progression-Free Survival (PFS) Rate at Month 36 in ITT Population [units: percent chance of being progression-free] Number (95% Confidence Interval)	15.5 (9.1 to 23.3)	8.6 (3.8 to 16.0)

3. Primary Outcome Measure:

Measure Title	Median Progression-Free Survival (PFS) in Testosterone Specific Evaluable Population
Measure Description	PFS was the time from randomization to the date of first documented PSA progression, or radiographic progression, or death due to prostate cancer in the absence of previous documentation of disease progression, whichever occurred first. Median PFS was estimated using the Kaplan-Meier method.
Time Frame	Randomization until PSA progression or radiographic progression or death due to prostate cancer, assessed up to Month 60
Safety Issue?	No

Analysis Population Description

Testosterone-specific evaluable population included all participants who recovered testosterone to non-castrate levels (50 ng/mL) following the completion of treatment of leuprolide with at least 1 follow-up PSA assessment.

Reporting Groups

	Description
Docetaxel+Leuprolide+Bicalutamide	Participants received docetaxel 75 milligram per square meter (mg/m^2) intravenous infusion over 1 hour every 3 weeks up to 10 cycles (3 week cycle) along with leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.
Leuprolide+Bicalutamide	Participants received leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.

Measured Values

	Docetaxel+Leuprolide+Bicalutamide	Leuprolide+Bicalutamide
Number of Participants Analyzed	122	124
Median Progression-Free Survival (PFS) in Testosterone Specific Evaluable Population [units: months] Median (95% Confidence Interval)	25.7 (25.1 to 28.1)	24.7 (22.8 to 25.3)

4. Primary Outcome Measure:

Measure Title	Progression-Free Survival (PFS) Rate at Month 36 in Testosterone Specific Evaluable Population
Measure Description	PFS rate at Month 36 was defined as probability of being progression-free at Month 36. PFS rate was estimated using the Kaplan-Meier method.
Time Frame	Month 36
Safety Issue?	No

Analysis Population Description

Testosterone-specific evaluable population included all participants who recovered testosterone to non-castrate levels (50 ng/mL) following completion of treatment of leuprolide with at least 1 follow-up PSA assessment.

Reporting Groups

	Description
Docetaxel+Leuprolide+Bicalutamide	Participants received docetaxel 75 milligram per square meter (mg/m^2) intravenous infusion over 1 hour every 3 weeks up to 10 cycles (3 week cycle) along with leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.
Leuprolide+Bicalutamide	Participants received leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.

Measured Values

	Docetaxel+Leuprolide+Bicalutamide	Leuprolide+Bicalutamide
Number of Participants Analyzed	122	124
Progression-Free Survival (PFS) Rate at Month 36 in Testosterone Specific Evaluable Population [units: percent chance of being progression-free] Number (95% Confidence Interval)	15.8 (9.0 to 24.3)	9.1 (4.0 to 16.7)

5. Secondary Outcome Measure:

Measure Title	Overall Survival (OS): Number of Participants Who Died (All Cause)
Measure Description	The OS was the time interval from the date of randomization to the date of death due to any cause. OS was to be analyzed using the Kaplan-Meier method. However, the analysis was not performed due to insufficient number of events. Reported is the number of participants who died from any cause.

Time Frame	Randomization until death due to any cause, assessed up to Month 60
Safety Issue?	No

Analysis Population Description
ITT population.

Reporting Groups

	Description
Docetaxel+Leuprolide+Bicalutamide	Participants received docetaxel 75 milligram per square meter (mg/m^2) intravenous infusion over 1 hour every 3 weeks up to 10 cycles (3 week cycle) along with leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.
Leuprolide+Bicalutamide	Participants received leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.

Measured Values

	Docetaxel+Leuprolide+Bicalutamide	Leuprolide+Bicalutamide
Number of Participants Analyzed	207	206
Overall Survival (OS): Number of Participants Who Died (All Cause) [units: participants]	4	11

6. Secondary Outcome Measure:

Measure Title	Cancer-Specific Survival: Number of Participants Who Died (Cancer-Specific)
Measure Description	The cancer-specific survival was the time from the date of randomization to the date of death due to prostate cancer. Cancer-specific survival was to be analyzed using the Kaplan-Meier method. However, the analysis was not performed due to insufficient number of events. Reported is the number of participants who died from prostate cancer.
Time Frame	Randomization until death due to prostate cancer, assessed up to Month 60
Safety Issue?	No

Analysis Population Description
ITT population.

Reporting Groups

	Description
Docetaxel+Leuprolide+Bicalutamide	Participants received docetaxel 75 milligram per square meter (mg/m^2) intravenous infusion over 1 hour every 3 weeks up to 10 cycles (3 week cycle) along with leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.
Leuprolide+Bicalutamide	Participants received leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.

Measured Values

	Docetaxel+Leuprolide+Bicalutamide	Leuprolide+Bicalutamide
Number of Participants Analyzed	207	206
Cancer-Specific Survival: Number of Participants Who Died (Cancer-Specific) [units: participants]	2	3

7. Secondary Outcome Measure:

Measure Title	Change From Baseline in Functional Assessment of Cancer Therapy-Prostate (FACT-P) Total Score at End of Treatment (EOT)
Measure Description	FACT-P is a 39-item participant questionnaire which assesses physical well-being (7 items), social/family well-being (7 items), emotional well-being (6 items), functional well-being (7 items), and additional prostate cancer specific concerns (12 items). All items are scored from 0 (not at all) to 4 (very much). The total FACT-P score ranges from 0-156, with higher scores representing a better quality of life with fewer symptoms. A score of 156 represents the best outcome.
Time Frame	Baseline, EOT (up to Month 18)
Safety Issue?	No

Analysis Population Description

ITT population. Here “N” (number of participants analyzed) signifies participants who were evaluable for this measure and “n” signifies participants evaluable at each time-point for each treatment arm, respectively.

Reporting Groups

	Description
Docetaxel+Leuprolide+Bicalutamide	Participants received docetaxel 75 milligram per square meter (mg/m^2) intravenous infusion over 1 hour every 3 weeks up to 10 cycles (3 week cycle) along with leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.

	Description
Leuprolide+Bicalutamide	Participants received leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.

Measured Values

	Docetaxel+Leuprolide+Bicalutamide	Leuprolide+Bicalutamide
Number of Participants Analyzed	206	205
Change From Baseline in Functional Assessment of Cancer Therapy-Prostate (FACT-P) Total Score at End of Treatment (EOT) [units: units on a scale] Mean (Standard Deviation)		
Baseline (n=206, 205)	121.4 (18.32)	119.6 (17.95)
Change at EOT (n=186, 184)	-4.9 (13.55)	-3.4 (14.78)

8. Secondary Outcome Measure:

Measure Title	Change From Baseline in Functional Assessment of Cancer Therapy-Prostate (FACT-P) Trial Outcome Index (TOI) Score at EOT
Measure Description	Physical well-being, functional well-being, and prostate cancer concerns sub-scales of the FACT-P questionnaire were combined to calculate TOI. Total TOI score ranges from 0 to 104, with higher scores representing a better quality of life with fewer symptoms.
Time Frame	Baseline, EOT (up to Month 18)
Safety Issue?	No

Analysis Population Description

ITT population. Here “N” (number of participants analyzed) signifies participants who were evaluable for this measure and “n” signifies participants evaluable at each time-point for each treatment arm, respectively.

Reporting Groups

	Description
Docetaxel+Leuprolide+Bicalutamide	Participants received docetaxel 75 milligram per square meter (mg/m^2) intravenous infusion over 1 hour every 3 weeks up to 10 cycles (3 week cycle) along with leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.
Leuprolide+Bicalutamide	Participants received leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.

Measured Values

	Docetaxel+Leuprolide+Bicalutamide	Leuprolide+Bicalutamide
Number of Participants Analyzed	206	206
Change From Baseline in Functional Assessment of Cancer Therapy-Prostate (FACT-P) Trial Outcome Index (TOI) Score at EOT [units: units on a scale] Mean (Standard Deviation)		
Baseline (n=206, 206)	82.1 (12.58)	80.4 (12.52)
Change at EOT (n=187, 187)	-5.4 (10.19)	-3.1 (11.83)

9. Secondary Outcome Measure:

Measure Title	Change From Baseline in Multidimensional Assessment of Fatigue (MAF) Index Score at EOT
Measure Description	MAF scale consists of 16-items to measure 4 dimensions of fatigue during past week: severity (Item 1-2), distress (Item 3), degree of interference in activities of daily living (Item 4-14), and timing (Item 15-16). Item 1-14 are scored on a numeric rating scale from 1 to 10, where higher score indicate more severity/distress/interference. Item 15-16 had multiple choice responses (4 responses each). Scale Index was calculated using Item 1-15, in following steps: 1) Item 15 score converted to 1-10 scale by multiplying the score with 2.5; 2) Average score was calculated from Item 4-14; 3) Finally scale index was calculated by adding Items 1, 2, 3 scores with average score from step 2 and converted score of Item 15 from step 1. Total MAF scale index score ranges 1 (no fatigue) to 50 (severe fatigue).
Time Frame	Baseline, EOT (up to Month 18)
Safety Issue?	No

Analysis Population Description

ITT population. Here “N” (number of participants analyzed) signifies participants who were evaluable for this measure and “n” signifies participants evaluable at each time-point for each treatment arm, respectively.

Reporting Groups

	Description
Docetaxel+Leuprolide+Bicalutamide	Participants received docetaxel 75 milligram per square meter (mg/m^2) intravenous infusion over 1 hour every 3 weeks up to 10 cycles (3 week cycle) along with leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.
Leuprolide+Bicalutamide	Participants received leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.

Measured Values

	Docetaxel+Leuprolide+Bicalutamide	Leuprolide+Bicalutamide
Number of Participants Analyzed	168	171
Change From Baseline in Multidimensional Assessment of Fatigue (MAF) Index Score at EOT [units: units on a scale] Mean (Standard Deviation)		
Baseline (n=168, 171)	16.4 (7.33)	16.6 (7.93)
Change at EOT (n=127, 144)	4.0 (8.93)	2.6 (8.60)

10. Secondary Outcome Measure:

Measure Title	Change From Baseline in Erectile Function Domain of International Index of Erectile Function (EF-IIEF) Total Score at EOT
Measure Description	EF-IIEF is a 6-item erectile function domain of IIEF. It consists of Question 1, 2, 3, 4, 5, and 15 of IIEF questionnaire. 5 questions are scored from 0 (no activity) to 5 (very high activity) and 1 question is scored from 1 (very low activity) to 5 (very high activity). Total EF-IIEF score ranges from 1 to 30, where higher score indicates high activity.
Time Frame	Baseline, EOT (up to Month 18)
Safety Issue?	No

Analysis Population Description

ITT population. Here "N" (number of participants analyzed) signifies participants who were evaluable for this measure and "n" signifies participants evaluable at each time-point for each treatment arm, respectively.

Reporting Groups

	Description
Docetaxel+Leuprolide+Bicalutamide	Participants received docetaxel 75 milligram per square meter (mg/m^2) intravenous infusion over 1 hour every 3 weeks up to 10 cycles (3 week cycle) along with leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.
Leuprolide+Bicalutamide	Participants received leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.

Measured Values

	Docetaxel+Leuprolide+Bicalutamide	Leuprolide+Bicalutamide
Number of Participants Analyzed	201	205

	Docetaxel+Leuprolide+Bicalutamide	Leuprolide+Bicalutamide
Change From Baseline in Erectile Function Domain of International Index of Erectile Function (EF-IIEF) Total Score at EOT [units: units on a scale] Mean (Standard Deviation)		
Baseline (n=201, 205)	6.4 (8.30)	6.8 (8.25)
Change at EOT (n=180, 186)	-3.1 (7.15)	-3.3 (7.11)

11. Other Pre-specified Outcome Measure:

Measure Title	Number of Participants With Treatment-Emergent Adverse Events (TEAEs)
Measure Description	TEAE: any adverse event (AE) that occurred or worsened during the on-treatment period, which was the period from first administration of study treatment until 30 days after last administration of study treatment. AE: any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. Serious AE: an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly, or medically important. Drug-related AEs were any untoward medical occurrences attributed to study drug in a participant who received study drug. National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 3.0 Grade 3 (severe) and Grade 4 (life threatening/ disabling) TEAEs were also reported.
Time Frame	From first administration of study treatment until 30 days after the last administration of study treatment
Safety Issue?	Yes

Analysis Population Description

Safety population included all randomized participants who received at least part of one dose of any of the study drugs.

Reporting Groups

	Description
Docetaxel+Leuprolide+Bicalutamide	Participants received docetaxel 75 milligram per square meter (mg/m^2) intravenous infusion over 1 hour every 3 weeks up to 10 cycles (3 week cycle) along with leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.
Leuprolide+Bicalutamide	Participants received leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.

Measured Values

	Docetaxel+Leuprolide+Bicalutamide	Leuprolide+Bicalutamide
Number of Participants Analyzed	196	204
Number of Participants With Treatment-Emergent Adverse Events (TEAEs) [units: participants]		
Any TEAE	188	163
Any Serious AE	49	20
Any TEAE Resulting in Death	0	1
Any TEAE Leading to any Treatment Discontinuation	35	1
Any Grade 3-4 TEAE	94	22
Docetaxel Related TEAE	183	NA [1]
Leuprolide Related TEAE	109	136
Bicalutamide Related TEAE	52	74
Any Treatment Related TEAE	184	136
Any Grade 3-4 Serious TEAE	43	14
Any TEAE Leading to Interruption of any Treatment	77	1

[1] Participants in this treatment arm did not receive docetaxel.

Reported Adverse Events

Time Frame	From signature of the informed consent form up to the last visit in the study
Additional Description	The analysis was performed on safety population, defined as all randomized participants who received at least part of one dose of any of the study drugs, and included all TEAEs that developed or worsened from first administration of study treatment until 30 days after last administration of study treatment.

Reporting Groups

	Description
Docetaxel+Leuprolide+Bicalutamide	Participants received docetaxel 75 milligram per square meter (mg/m^2) intravenous infusion over 1 hour every 3 weeks up to 10 cycles (3 week cycle) along with leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.
Leuprolide+Bicalutamide	Participants received leuprolide 22.5 mg injection subcutaneously every 12 weeks up to 18 months and bicalutamide 50 mg tablet orally once daily for first 4 weeks of treatment.

Serious Adverse Events

	Docetaxel+Leuprolide+Bicalutamide	Leuprolide+Bicalutamide
	Affected/At Risk (%)	Affected/At Risk (%)
Total	49/196 (25%)	20/204 (9.8%)
Blood and lymphatic system disorders		
ANAEMIA [A] *	1/196 (0.51%)	0/204 (0%)
FEBRILE NEUTROPENIA [A] *	11/196 (5.61%)	0/204 (0%)
LYMPHADENOPATHY [A] *	0/196 (0%)	1/204 (0.49%)
NEUTROPENIA [A] *	9/196 (4.59%)	0/204 (0%)
Cardiac disorders		
ACUTE MYOCARDIAL INFARCTION [A] *	1/196 (0.51%)	0/204 (0%)
ANGINA PECTORIS [A] *	1/196 (0.51%)	2/204 (0.98%)
AORTIC VALVE DISEASE [A] *	1/196 (0.51%)	0/204 (0%)
ATRIAL FIBRILLATION [A] *	3/196 (1.53%)	1/204 (0.49%)
MYOCARDIAL INFARCTION [A] *	1/196 (0.51%)	0/204 (0%)
MYOCARDIAL ISCHAEMIA [A] *	0/196 (0%)	1/204 (0.49%)
NODAL ARRHYTHMIA [A] *	1/196 (0.51%)	0/204 (0%)
Eye disorders		
RETINAL DETACHMENT [A] *	0/196 (0%)	1/204 (0.49%)
Gastrointestinal disorders		

	Docetaxel+Leuprolide+Bicalutamide	Leuprolide+Bicalutamide
	Affected/At Risk (%)	Affected/At Risk (%)
ABDOMINAL WALL HAEMATOMA [A] *	0/196 (0%)	1/204 (0.49%)
COLITIS [A] *	0/196 (0%)	1/204 (0.49%)
ENTEROCOLITIS [A] *	1/196 (0.51%)	0/204 (0%)
ENTEROVESICAL FISTULA [A] *	1/196 (0.51%)	0/204 (0%)
GASTROOESOPHAGEAL REFLUX DISEASE [A] *	1/196 (0.51%)	0/204 (0%)
HAEMATEMESIS [A] *	1/196 (0.51%)	0/204 (0%)
HAEMATOCHEZIA [A] *	1/196 (0.51%)	0/204 (0%)
INGUINAL HERNIA [A] *	1/196 (0.51%)	0/204 (0%)
INTESTINAL PERFORATION [A] *	1/196 (0.51%)	0/204 (0%)
PERITONITIS [A] *	1/196 (0.51%)	0/204 (0%)
SMALL INTESTINAL OBSTRUCTION [A] *	1/196 (0.51%)	0/204 (0%)
General disorders		
CHEST PAIN [A] *	1/196 (0.51%)	1/204 (0.49%)
GENERALISED OEDEMA [A] *	1/196 (0.51%)	0/204 (0%)
HERNIA [A] *	1/196 (0.51%)	0/204 (0%)
MUCOSAL INFLAMMATION [A] *	1/196 (0.51%)	0/204 (0%)
NON CARDIAC CHEST PAIN [A] *	1/196 (0.51%)	0/204 (0%)
PYREXIA [A] *	1/196 (0.51%)	0/204 (0%)
Immune system disorders		
ANAPHYLACTOID REACTION [A] *	1/196 (0.51%)	0/204 (0%)
Infections and infestations		
APPENDICITIS PERFORATED [A] *	0/196 (0%)	1/204 (0.49%)

	Docetaxel+Leuprolide+Bicalutamide	Leuprolide+Bicalutamide
	Affected/At Risk (%)	Affected/At Risk (%)
BACTERAEMIA [A] *	0/196 (0%)	1/204 (0.49%)
CYSTITIS [A] *	0/196 (0%)	1/204 (0.49%)
DIVERTICULITIS [A] *	1/196 (0.51%)	0/204 (0%)
GENITOURINARY TRACT INFECTION [A] *	1/196 (0.51%)	0/204 (0%)
GROIN ABSCESS [A] *	0/196 (0%)	1/204 (0.49%)
NEUTROPENIC INFECTION [A] *	1/196 (0.51%)	0/204 (0%)
PERIDIVERTICULAR ABSCESS [A] *	1/196 (0.51%)	0/204 (0%)
PNEUMONIA [A] *	3/196 (1.53%)	0/204 (0%)
UROSEPSIS [A] *	0/196 (0%)	1/204 (0.49%)
Injury, poisoning and procedural complications		
FEMUR FRACTURE [A] *	1/196 (0.51%)	1/204 (0.49%)
JOINT DISLOCATION [A] *	0/196 (0%)	1/204 (0.49%)
POST PROCEDURAL HAEMORRHAGE [A] *	1/196 (0.51%)	0/204 (0%)
Investigations		
ALANINE AMINOTRANSFERASE INCREASED [A] *	1/196 (0.51%)	0/204 (0%)
ASPARTATE AMINOTRANSFERASE INCREASED [A] *	1/196 (0.51%)	0/204 (0%)
Metabolism and nutrition disorders		
DEHYDRATION [A] *	1/196 (0.51%)	0/204 (0%)
DIABETES MELLITUS [A] *	2/196 (1.02%)	0/204 (0%)
HYPERKALAEMIA [A] *	1/196 (0.51%)	0/204 (0%)
TYPE 2 DIABETES MELLITUS [A] *	0/196 (0%)	1/204 (0.49%)

	Docetaxel+Leuprolide+Bicalutamide	Leuprolide+Bicalutamide
	Affected/At Risk (%)	Affected/At Risk (%)
Musculoskeletal and connective tissue disorders		
ARTHRITIS [A] *	1/196 (0.51%)	1/204 (0.49%)
SPINAL COLUMN STENOSIS [A] *	1/196 (0.51%)	0/204 (0%)
SYNOVIAL CYST [A] *	0/196 (0%)	1/204 (0.49%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
COLON CANCER [A] *	0/196 (0%)	2/204 (0.98%)
GASTRIC CANCER [A] *	1/196 (0.51%)	0/204 (0%)
Nervous system disorders		
DIZZINESS [A] *	1/196 (0.51%)	0/204 (0%)
LOSS OF CONSCIOUSNESS [A] *	1/196 (0.51%)	0/204 (0%)
MYASTHENIA GRAVIS [A] *	1/196 (0.51%)	0/204 (0%)
SCIATICA [A] *	1/196 (0.51%)	0/204 (0%)
SYNCOPE [A] *	1/196 (0.51%)	0/204 (0%)
Renal and urinary disorders		
BLADDER NECK OBSTRUCTION [A] *	0/196 (0%)	1/204 (0.49%)
HYDRONEPHROSIS [A] *	0/196 (0%)	1/204 (0.49%)
Respiratory, thoracic and mediastinal disorders		
PNEUMOMEDIASTINUM [A] *	0/196 (0%)	1/204 (0.49%)
PULMONARY EMBOLISM [A] *	2/196 (1.02%)	1/204 (0.49%)
Vascular disorders		
ILIAC ARTERY STENOSIS [A] *	1/196 (0.51%)	0/204 (0%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA 14.1

Other Adverse Events

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

	Docetaxel+Leuprolide+Bicalutamide	Leuprolide+Bicalutamide
	Affected/At Risk (%)	Affected/At Risk (%)
Total	185/196 (94.39%)	139/204 (68.14%)
Blood and lymphatic system disorders		
ANAEMIA [A] *	18/196 (9.18%)	2/204 (0.98%)
NEUTROPENIA [A] *	31/196 (15.82%)	0/204 (0%)
Eye disorders		
LACRIMATION INCREASED [A] *	31/196 (15.82%)	0/204 (0%)
Gastrointestinal disorders		
CONSTIPATION [A] *	28/196 (14.29%)	9/204 (4.41%)
DIARRHOEA [A] *	64/196 (32.65%)	7/204 (3.43%)
DYSPEPSIA [A] *	17/196 (8.67%)	0/204 (0%)
GASTROOESOPHAGEAL REFLUX DISEASE [A] *	10/196 (5.1%)	3/204 (1.47%)
NAUSEA [A] *	56/196 (28.57%)	11/204 (5.39%)
STOMATITIS [A] *	20/196 (10.2%)	0/204 (0%)
VOMITING [A] *	19/196 (9.69%)	2/204 (0.98%)
General disorders		
ASTHENIA [A] *	19/196 (9.69%)	3/204 (1.47%)
FATIGUE [A] *	104/196 (53.06%)	58/204 (28.43%)
OEDEMA PERIPHERAL [A] *	66/196 (33.67%)	11/204 (5.39%)
PYREXIA [A] *	24/196 (12.24%)	0/204 (0%)
Infections and infestations		
NASOPHARYNGITIS [A] *	12/196 (6.12%)	6/204 (2.94%)

	Docetaxel+Leuprolide+Bicalutamide	Leuprolide+Bicalutamide
	Affected/At Risk (%)	Affected/At Risk (%)
UPPER RESPIRATORY TRACT INFECTION [A] *	11/196 (5.61%)	2/204 (0.98%)
Investigations		
ALANINE AMINOTRANSFERASE INCREASED [A] *	12/196 (6.12%)	7/204 (3.43%)
WEIGHT DECREASED [A] *	11/196 (5.61%)	2/204 (0.98%)
WEIGHT INCREASED [A] *	13/196 (6.63%)	13/204 (6.37%)
Metabolism and nutrition disorders		
DECREASED APPETITE [A] *	24/196 (12.24%)	3/204 (1.47%)
HYPERGLYCAEMIA [A] *	15/196 (7.65%)	2/204 (0.98%)
Musculoskeletal and connective tissue disorders		
ARTHRALGIA [A] *	40/196 (20.41%)	17/204 (8.33%)
BACK PAIN [A] *	19/196 (9.69%)	8/204 (3.92%)
BONE PAIN [A] *	13/196 (6.63%)	1/204 (0.49%)
MYALGIA [A] *	31/196 (15.82%)	6/204 (2.94%)
PAIN IN EXTREMITY [A] *	34/196 (17.35%)	12/204 (5.88%)
Nervous system disorders		
DIZZINESS [A] *	15/196 (7.65%)	8/204 (3.92%)
DYSGEUSIA [A] *	51/196 (26.02%)	1/204 (0.49%)
HEADACHE [A] *	21/196 (10.71%)	10/204 (4.9%)
HYPOAESTHESIA [A] *	16/196 (8.16%)	3/204 (1.47%)
NEUROPATHY PERIPHERAL [A] *	37/196 (18.88%)	3/204 (1.47%)
PARAESTHESIA [A] *	19/196 (9.69%)	1/204 (0.49%)

	Docetaxel+Leuprolide+Bicalutamide	Leuprolide+Bicalutamide
	Affected/At Risk (%)	Affected/At Risk (%)
PERIPHERAL SENSORY NEUROPATHY [A] *	31/196 (15.82%)	4/204 (1.96%)
Psychiatric disorders		
INSOMNIA [A] *	31/196 (15.82%)	9/204 (4.41%)
Renal and urinary disorders		
POLLAKIURIA [A] *	15/196 (7.65%)	7/204 (3.43%)
URINARY INCONTINENCE [A] *	12/196 (6.12%)	17/204 (8.33%)
Respiratory, thoracic and mediastinal disorders		
COUGH [A] *	26/196 (13.27%)	4/204 (1.96%)
DYSPNOEA [A] *	25/196 (12.76%)	11/204 (5.39%)
EPISTAXIS [A] *	14/196 (7.14%)	0/204 (0%)
HICCUPS [A] *	12/196 (6.12%)	0/204 (0%)
Skin and subcutaneous tissue disorders		
ALOPECIA [A] *	110/196 (56.12%)	3/204 (1.47%)
DRY SKIN [A] *	15/196 (7.65%)	2/204 (0.98%)
ERYTHEMA [A] *	11/196 (5.61%)	0/204 (0%)
NAIL DISORDER [A] *	50/196 (25.51%)	1/204 (0.49%)
RASH [A] *	18/196 (9.18%)	1/204 (0.49%)
Vascular disorders		
HOT FLUSH [A] *	82/196 (41.84%)	118/204 (57.84%)
HYPERTENSION [A] *	8/196 (4.08%)	12/204 (5.88%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA 14.1

Limitations and Caveats

[Not specified]

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.

The investigator shall provide the Steering Committee a copy of any manuscript, abstract or oral communication derived from the study for review and comment at least 30 days in advance of any submission. The Sponsor's representatives shall have the right to review and/or delay any publication or presentation to prevent disclosure of Sponsor's confidential information and preserve intellectual property rights.

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