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History of Changes for Study: NCT02924766

A Safety and Pharmacokinetics Study of Niraparib Plus Apalutamide in Men With Metastatic Castration-Resistant Prostate Cancer (BEDIVERE)

[Latest version \(submitted July 16, 2020\) on ClinicalTrials.gov](#)

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in green.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	☒	☒	<u>October 4, 2016</u>	None (earliest Version on record)
2	☐	☐	<u>November 3, 2016</u>	Recruitment Status, Study Status, Contacts/Locations and References
3	☐	☐	<u>April 21, 2017</u>	Arms and Interventions, Study Status, Outcome Measures, Study Identification, Contacts/Locations, Eligibility, Study Design, Study Description and Oversight
4	☐	☐	<u>May 12, 2017</u>	Arms and Interventions, Study Status, Eligibility and Study Identification
5	☐	☐	<u>June 23, 2017</u>	Study Status and Contacts/Locations

Version	A	B	Submitted Date	Changes
6	☐	☐	<u>August 17, 2017</u>	Study Status
7	☐	☐	<u>November 9, 2017</u>	Study Status and Contacts/Locations
8	☐	☐	<u>December 6, 2017</u>	Study Status
9	☐	☐	<u>February 1, 2018</u>	Study Status and Contacts/Locations
10	☐	☐	<u>June 6, 2018</u>	Study Status
11	☐	☐	<u>October 11, 2018</u>	Study Status and Contacts/Locations
12	☐	☐	<u>November 13, 2018</u>	Recruitment Status, Contacts/Locations, Study Status, Study Design and References
13	☐	☐	<u>December 6, 2018</u>	Study Status
14	☐	☐	<u>February 22, 2019</u>	Study Status
15	☐	☐	<u>May 23, 2019</u>	Study Status
16	☐	☐	<u>June 20, 2019</u>	Study Status
17	☐	☐	<u>July 26, 2019</u>	Recruitment Status and Study Status
18	☐	☐	<u>July 16, 2020</u>	Study Status and References

Compare

Comparison Format:

☒ Merged☐ Side-by-Side[Scroll up to access the controls](#)**Study NCT02924766****Submitted Date: October 4, 2016 (v1)****Study Identification**

Unique Protocol ID: CR108230

Brief Title: A Safety and Pharmacokinetics Study of Niraparib Plus
Apalutamide in Men With Metastatic Castration-
Resistant Prostate Cancer (BEDIVERE)

Official Title:

A Safety and Pharmacokinetics Study of Niraparib Plus
Apalutamide in Men With Metastatic Castration-
Resistant Prostate Cancer

Secondary IDs: 2016-002694-35 [EudraCT Number]
64091742PCR1001 [Janssen Research & Development,
LLC]

Study Status

Record Verification: October 2016

Overall Status: Not yet recruiting

Study Start: October 2016

Primary Completion: July 2017 [Anticipated]

Study Completion: May 2018 [Anticipated]

First Submitted: October 4, 2016

First Submitted that Met QC Criteria:

First Submitted that Met QC Criteria:

First Posted: October 5, 2016 [Estimate]

Last Update Submitted that Met QC Criteria:

Last Update Submitted that Met QC Criteria:

Last Update Posted: October 5, 2016 [Estimate]

Sponsor/Collaborators

Sponsor: Janssen Research & Development, LLC

Responsible Party: Sponsor

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: No

Study Description

Brief Summary: The purpose of this study is to assess the safety and pharmacokinetics of niraparib when administered in combination with apalutamide in men with metastatic castration resistant prostate cancer (mCRPC) who may or may not have deoxyribonucleic acid (DNA)-repair anomalies.

Detailed Description:

Conditions

Conditions: Prostatic Neoplasms

Keywords:

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 1

Interventional Study Model: Single Group Assignment

Number of Arms: 1

Masking: None (Open Label)

Allocation: N/A

Enrollment: 30 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Niraparib + Apalutamide Participants will receive initial starting dose of niraparib 200 milligram (mg) once daily in combination with apalutamide 240 mg (4*60 mg) once daily in dose selection phase (Part 1) of the study to determine the recommended Phase 2 dose (RP2D) of niraparib, followed by a dose expansion phase (Part 2) study to further explore safety and assess antitumor activity of the combination niraparib and apalutamide. Part 1 comprise a standard 3+3 dose selection phase for dose escalation to 300 mg (the maximum dose), or de-escalation to 100 mg niraparib (the minimum dose).	Drug: Niraparib Participants will start with niraparib 200 mg per day orally. Drug: Apalutamide Participants will receive apalutamide 240 mg (4*60 mg) once daily orally.

Outcome Measures

Primary Outcome Measures:

1.

Determine Recommended Phase 2 dose (RP2D) of Niraparib in Combination With 240 milligram (mg) Apalutamide (Part 1)

RP2D will be defined as the highest dose of study drug at which less than 33 percent (%) of participants experience dose limiting toxicity (DLT).

[Time Frame: Up to 28 Days]

2. Number of Participants With Incidence and Severity of Adverse Events (Part 2)
Number of participants will be assessed to further explore safety and antitumor activity in Part 2 (dose expansion) of study.

[Time Frame: Up to 30 days after last dose]

Secondary Outcome Measures:

3. Maximum Observed Plasma Concentration (C_{max})
Maximum observed plasma concentration (C_{max}) will be assessed for niraparib and apalutamide.

[Time Frame: Predose (Cycle 1 Day 1) up to Cycle 1 Day 28 (24 hours)]

4. Area Under the Plasma Concentration-Time Curve From Time Zero to 24 Hours (AUC [0-24])
Area under plasma concentration-time curve from time 0 to time 24 (AUC [0-24]) hours after dosing will be assessed for niraparib and apalutamide.

[Time Frame: Predose (Cycle 1 Day 1) up to Cycle 1 Day 28 (24 hours)]

5. Time to Reach the Maximum Observed Plasma Concentration (T_{max})
Time to reach the maximum plasma concentration (T_{max}) will be assessed for niraparib and apalutamide.

[Time Frame: Predose (Cycle 1 Day 1) up to Cycle 1 Day 28 (24 hours)]

6. Minimum Observed Plasma Concentration (C_{min})
Minimum observed plasma concentration (C_{min}) will be assessed for niraparib and apalutamide.

[Time Frame: Predose (Cycle 1 Day 1) up to Cycle 1 Day 28 (24 hours)]

7. Prostate Specific Antigen (PSA) Response at 12 Weeks
Based on Prostate Cancer Working Group 3 (PCWG3) recommendations PSA response at 12 weeks defined as percent change from baseline (rise or fall) at 12 weeks using a waterfall plot.

[Time Frame: 12 Weeks]

- 8.

Maximum Prostate Specific Antigen (PSA) Decline

Based on Prostate Cancer Working Group 3 (PCWG3) recommendations

Maximum PSA decline defined as the maximum change (rise or fall) at any time using a waterfall plot.

[Time Frame: Baseline up to Day 28 (Cycle 4)]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: Male

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Greater than (>)18 years of age (or higher legal age of consent in the jurisdiction in which the study is taking place)
- At least 1 line of prior taxane-based chemotherapy
- At least 1 line of prior androgen receptor (AR) targeted therapy
- Progression of metastatic prostate cancer in the setting of castrate levels of testosterone less than equal to ($\leq$)50 nanogram per deciliter (ng/dL) on a gonadotropin releasing hormone analog (GnRHa), or history of bilateral orchiectomy at study entry defined as having one or more of the following: (a) Prostate Specific Antigen (PSA) progression defined by a minimum of 2 rising PSA levels with an interval of greater than equal to ($\geq$) 1 week between each determination. The PSA level at the screening visit should be $\geq$ 2 microgram per liters (mcg/L) [2 ng/mL], (b) Radiographic progression of soft tissue or bone disease by Prostate Cancer Working Group 3 (PCWG3) criteria
- Must continue gonadotropin releasing hormone analog (GnRHa) during the course of the study if not surgically castrate

Exclusion Criteria:

- Prior treatment with a poly (adenosine diphosphate [ADP] ribose) polymerase (PARP) inhibitor
- Known history or current diagnosis of myelodysplastic syndrome (MDS)/acute myeloid leukemia (AML)
- Known symptomatic or impending cord compression, except if participant has received definitive treatment for this and demonstrates evidence of clinically stable disease
- Presence of uncontrolled hypertension (systolic blood pressure [BP] >160 millimeter of mercury (mmHg) or diastolic BP >100 mmHg). Participants with a history of hypertension are allowed, provided that BP is controlled to within these limits by anti-hypertensive treatment
- Current or prior treatment with anti-epileptic medications for the treatment of seizures

Contacts/Locations

Central Contact: This study is not yet recruiting patients. Please check back for future recruiting sites, or email

Email: JNJ.CT@sylogent.com

Study Officials: Janssen Research & Development, LLC Clinical Trial Study Director

Janssen Research & Development, LLC

Locations: **United States, California**

West Hollywood, California, United States

United States, Kentucky

Louisville, Kentucky, United States

United States, Oregon

Portland, Oregon, United States

United States, South Carolina

Myrtle Beach, South Carolina, United States

Canada, British Columbia

Vancouver, British Columbia, Canada

Canada, Quebec

Montreal, Quebec, Canada



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