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A study of JNJ-80038114 in participants with advanced stage prostate cancer

Submission date 04/01/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 13/01/2023	**Overall study status** Completed	
Last Edited 26/10/2026	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims

The purpose of this study is to see if a new study drug can be used in future studies for the treatment of prostate cancer. During the study, side effects caused by the study drug will be followed closely, as well as how long the study drug stays in the body and how the body responds to it.

This is the first time that the study drug is being tested in humans. It is not approved for use by humans in any country.

Therefore, Part 1 of the study will start with the administration of a low dose of the study drug. After reviewing the results obtained at each dose level, it will be decided whether or how much to increase the dose for subsequent participants.

Who can participate?

This study will include participants aged 18 years and over with metastatic castration-resistant prostate cancer.

What does the study involve?

This study consists of a screening phase, a treatment phase and an end-of-treatment visit. All participants will receive the study drug via subcutaneous (below the skin) injections. The dose and frequency of the injections will depend on when a participant enters the study.

The duration of participation is determined by the duration of the study drug administration. Administration of the study drug will last as long as a participant benefits and does not have unmanageable side effects. In addition, participants and physicians can decide to stop the study drug at any time.

At study visits, a participant will have procedures such as blood and urine tests, ECG, physical exam, CT / MRI or bone scan. An additional fresh tumour biopsy may be collected during Part 2 of the study. Hospitalisation will also be required to monitor for any side effects during the first one or more doses of the study drug in Part 1.

What are the possible benefits and risks of participating?

This is the first study of this study drug in humans. It is possible that taking part in this study could improve a participant’s condition, but this is not guaranteed to happen.

During the study, a participant’s condition may stay the same or get worse.

Based on clinical trials of other active substances that target prostatespecific membrane antigen (also referred to as PSMA, a common protein in patients with prostate cancer) and the immune system, potential side effects have been outlined in the participant information sheet. This sheet will be signed by every participant agreeing to participate in the study and includes a section describing these potential side effects.
This is the first time the study drug will be given to humans, so we do not yet know if these potential side effects will occur or how frequently they may occur. Different side effects may occur. There may be risks to using the study drug that we don't know yet.
Tests and procedures will be done during the study to monitor side effects. Participants will also be educated to report any symptoms they experience during the study to their study doctor, even if they do not think the side effects are related to the study drug or procedures.

Where is the study run from?
Janssen Research & Development, LLC (Belgium) is the Sponsor of this study.
Participating centers (Hospitals) are located in the UK, US, France and Germany.

When is the study starting and how long is it expected to run for?
January 2022 to September 2024

Who is funding the study?
Janssen Research & Development, LLC (Belgium)

Who is the main contact?
Larissa Bates, janssenukregistryqueries@its.jnj.com

Contact information

Type(s)
Scientific

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ClinicalTrials.gov (NCT)
NCT05441501

Clinical Trials Information System (CTIS)
2022-001263-27

Integrated Research Application System (IRAS)
1005794

Central Portfolio Management System (CPMS)
53090

Protocol serial number
80038114PCR1001

Study information

Scientific Title
A phase 1 study of JNJ-80038114, a T-Cell redirecting agent targeting prostate specific membrane antigen (PSMA), for advanced stage prostate cancer

Study objectives
The main goals of this study are:
1. To determine the appropriate doses of the study drug and,
2. To evaluate any side effects.

The secondary goals of this study are:
1. To evaluate the cancer cells' response to the study drug and,
2. To provide an understanding of how the body reacts to the study drug and how long the study drug remains in the body.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/10/2022, West London and GTAC Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 207 1048 007; westlondon.rec@hra.nhs.uk), ref: 22/LO/0556

Primary study design
Interventional

Study design
Interventional non-randomized open-label multicenter study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Prostate cancer

Interventions
The study is split into two parts:
Part 1, dose-escalation: Participants will receive JNJ-80038114. The dose levels will be escalated based on the dose-limiting toxicities (DLTs) observed and then reviewed by the study evaluation team (SET).

Part 2, dose expansion: Participants will receive JNJ-80038114 at the recommended Phase 2 dose (RP2D) determined in Part 1.

Duration of participation is determined by the duration of study drug administration: administration of the study drug will last as long as a participant is receiving benefit and does not have unmanageable side effects. In addition, participant and physician can decide to stop the study drug at any time. There will be just one FU visit at 30-days post treatment.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
JNJ-80038114

Primary outcome(s)
The timeframe for monitoring/measuring each of these is up to 2 years and 6 months:
Parts 1 and 2:
1. Number of Participants With Adverse Events (AEs). An AE is any untoward medical occurrence in a participant participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/ biological agent under study.
2. Number of Participants With AEs by Severity. Severity will be graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 5.0.

Severity scale ranges from Grade 1 (Mild) to Grade 5 (Death). Grade 1= Mild, Grade 2= Moderate, Grade 3= Severe, Grade 4= Life-threatening and Grade 5= Death related to adverse event. Cytokine release syndrome (CRS) and associated neurologic toxicity events will be graded according to the American Society for Transplantation and Cellular Therapy (ASTCT) guidelines.

Part 1 only:
3. Number of Participants With Dose-Limiting Toxicity (DLT) . Number of participants with DLT will be reported. The DLTs are specific adverse events and are defined as any of the following: high grade non-hematologic toxicity, or hematologic toxicity.

Key secondary outcome(s)
The timeframe for monitoring/measuring each of these is up to 2 years and 6 months:
1. Serum Concentration of JNJ-80038114 - Serum concentration of JNJ-80038114 will be determined.
2. Systemic Cytokine Concentrations - Cytokine concentrations will be determined for biomarker assessment.
3. Serum Prostate Specific Antigen (PSA) Concentration - Serum PSA concentration will be determined.
4. Number of Participants With Antibodies to JNJ-80038114 - Serum samples will be analysed for the detection of antibodies to JNJ-80038114 using a validated assay method.
5. Objective Response Rate (ORR) - ORR is defined as the percentage of participants who have a partial response (PR) or better according to Prostate Cancer Working Group 3 (PCWG3) response criteria.
6. PSA Response Rate - PSA response rate is defined as the percentage of participants with a confirmed decline in PSA of 50 percent (%) or more from baseline.
7. Duration of Response (DOR) - DOR is defined as the duration from the date of initial documentation of a response (PR or better) to the date of first documented evidence of progressive disease, as defined in the PCWG3 response criteria, or death due to any cause, whichever occurs first.

Completion date
29/09/2024

Eligibility

Key inclusion criteria
1. 18 years and older
2. Metastatic castration-resistant prostate cancer (mCRPC) with confirmed adenocarcinoma of the prostate as defined by Prostate Cancer Working Group 3 (PCWG3)
3. Measurable or evaluable disease
4. At least 1 prior treatment for mCRPC
5. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
6. Adequate organ functions as defined by certain laboratory values
7. Must sign an informed consent form (ICF)
8. Participants must agree to use a highly effective form of birth control as guided by the study doctor

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
Male

Total final enrolment
49

Key exclusion criteria
1. Concurrent anticancer therapy
2. Severe or long-lasting side effects related to prior anticancer therapy
3. Known allergies to JNJ-80038114 or its excipients
4. Brain metastasis or known seizure history
5. Significant infections or lung, heart or other medical conditions

Date of first enrolment
14/12/2022

Date of final enrolment
19/01/2024

Locations

Countries of recruitment
United Kingdom

England

France

Germany

United States of America

Study participating centre
The Christie NHS Foundation Trust
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Study participating centre
The Royal Marsden Hospital (surrey)
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Study participating centre
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Study participating centre
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United States of America
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Sponsor information

Organisation
Janssen-Cilag International NV

Funder(s)

Funder type
Industry

Funder Name
Janssen-Cilag International NV

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study will be available upon request. The data sharing policy of the Janssen Pharmaceutical Companies of Johnson and Johnson is available at https://www.janssen.com/clinical trials/transparency. As noted on this site, requests for access to the study data can be submitted through the Yale Open Data Access (YODA) Project site at yoda.yale.edu.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No