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A Study of JNJ-90009530 in Relapsed or Refractory B-Cell non-Hodgkin Lymphoma (r/r B-NHL)

Submission date 09/01/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 01/03/2024	**Overall study status** Ongoing	
Last Edited 31/03/2026	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
B-cell non-Hodgkin lymphoma (NHL) is a cancer of white blood cells called B lymphocytes. The symptoms include enlarged lymph nodes (part of the body's immune system), fever and weight loss. Although treatments are available, it can come back after treatment or can be resistant to standard treatment. There is a need for development of safe and effective treatments.

JNJ-90009530 (study drug) is made from white blood cells (T-cells) of the participant. These cells are changed in laboratory to attack cancer cells when put back into the participant's blood. Study aim is to assess safety of JNJ-90009530 and to confirm the dose that can be safely given to participants.

Who can participate?
Adults with relapsed or refractory mature aggressive large B cell NHL, follicular lymphoma, and marginal zone lymphoma.

What does the study involve?
Study has 2 parts:
Run In: Participants will get JNJ-90009530 infusion in vein on Day 1.
Expansion: Participants will get JNJ-90009530 at the recommended phase 2 dose confirmed after
the Run-In.

The run in and dose expansion parts includes:
• Screening phase (28 days): To confirm eligibility.
• Apheresis/Enrolment: To collect certain type of white blood cells.
• Bridging therapy: Participants may get anticancer drug while JNJ-90009530 is being prepared.
• Lymphodepletion: Participants will get cyclophosphamide and fludarabine for 3 days to prepare the body for study drug.
• JNJ-90009530: Participants will get single JNJ-90009530 infusion in vein on Day 1.

• Post-infusion Follow-up (up to 90 days): Participants will be assessed for vital signs, pulse oximetry, laboratory parameters, biomarker.
• Post-treatment Follow-up (up to 2 years): Participants will be monitored for health.
• Long-term follow-up Period (up to 15 years)

After post-treatment follow-up participants will be monitored in long-term follow-up period for side effects, blood tests, vital signs and body scan to monitor disease status. Blood samples will be taken at multiple timepoints to find how body responds to study drug.

Total study duration will be approximately up to 16 years.

What are the possible benefits and risks of participating?
Participants will not receive any benefit from taking part in this study, but the information that is learned from the study may help people with B-cell non-Hodgkin lymphoma in the future.

This is a phase 1b dose confirmation study.

The expected risks for JNJ-90009530, based on how the drug works and results from laboratory studies are listed as cytokine release syndrome, immune effector cell-associated hemophagocytic lymphohistiocytosis-like syndrome, neurologic toxicities, including immune effector cell-associated neurotoxicity syndrome (ICANS) and non-ICANS, cytopenias including prolonged neutropenia, serious infection including viral reactivation, hypogammaglobulinemia, tumor lysis syndrome, hypersensitivity reaction including infusion related reactions, pneumonitis, subsequent primary
malignancy.

The participant information sheet and informed consent form, which will be signed by every participant agreeing to take part in the study, includes a detailed section outlining the risks to participating in the study. Participants may have none, some, or all of the possible side effects listed, and they may be mild, moderate, or severe. To minimise the risk associated with taking part, participants are frequently reviewed for any side effects and other medical events. If they have any side effects or are worried about them, or have any new or unusual symptoms, participants will be encouraged to talk with their study doctor. The study doctor will also be looking out for side effects and will provide appropriate medical care. There may also be side effects that the researchers do not expect or do not know about and that may be serious. Many side effects go away shortly after the intervention ends. However, sometimes side effects can be serious, long-lasting, or permanent. If a severe side effect or reaction occurs, the study doctor may need to stop the procedure. The study doctor will discuss the best way of managing any side effects with participants. There is always a chance that an unexpected or serious side effect may happen. This can happen to people who take this or any other drug.

Where is the study run from?
Janssen Research & Development, LLC

When is the study starting and how long is it expected to run for?
January 2024 to Jan 2040

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

Who is the main contact?
Aakta Al-Naqdi, aalnaqdi@its.jnj.com (Public)

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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)

2023-506259-97

Integrated Research Application System (IRAS)
1009316

ClinicalTrials.gov (NCT)
NCT05784441

Protocol serial number
90009530LYM1001, IRAS 1009316, CPMS 57721

Study information

Scientific Title
A Phase 1b Multicenter, Open-label, Study of JNJ-90009530, an Autologous Anti-CD20 CAR-T Cell Therapy in Adult Participants with Relapsed or Refractory B-cell Non- Hodgkin Lymphoma

Study objectives
Primary objectives:
1. To check if JNJ-90009530 is safe and well-tolerated.
2. To find the most effective dose (Recommended Phase 2 Dose [s]) of JNJ-90009530.

Secondary objectives:
1. To examine JNJ-90009530 in participants with relapsed (reoccurrence) B-cell non-Hodgkin lymphoma cancer or resistant to standard therapies to check how many people respond well overall (overall response rate), how quickly they respond (time to response) and how long the positive response lasts (duration of response).
2. To examine how JNJ-90009530 is absorbed, processed, and eliminated by the body (pharmacokinetics).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/02/2024, London - West London & GTAC Research Ethics Committee (2 Redman Place, London, E20 1JQ, United Kingdom; +44 (0)207 104 8241; westlondon.rec@hra.nhs.uk), ref: 24/LO/0010

Study design
Interventional non randomized

Primary study design
Interventional

Study type(s)
Efficacy, Safety

Health condition(s) or problem(s) studied
Non-Hodgkin Lymphoid Malignancies

Interventions

Current interventions as of 14/03/2025:

This is an open-label study, single drug administration study.
Up to 12 adult participants with r/r aggressive B-cell NHL may be enrolled into a Run In dose level.
After completion of the Run In, an aggressive lymphoma and an indolent lymphoma Dose Expansion cohort may open. Up to approx. 40 participants may be enrolled in each Dose Expansion cohort, allowing for up to approx. 92 participants to be enrolled in total.
For both the Run In and Dose Expansion, the study periods and durations for participants are:
• Screening (28 days): To confirm eligibility
• Apheresis/Enrolment: To collect certain type of white blood cells.
• Bridging therapy: Participants may get anticancer drug while JNJ-90009530 is being prepared.
• Lymphodepletion: Participants will get cyclophosphamide and fludarabine for 3 days to prepare the body for study drug.
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• Post-treatment follow-up (up to 2 years): Participants will be monitored for health.
• Long-term follow-up period (up to 15 years)

After post-treatment follow-up participants will be monitored in long-term follow-up period for side effects, blood tests, vital signs and body scan to monitor disease status. Blood samples will be taken at multiple timepoints to find how body responds to study drug. Total study duration will be approximately up to 16 years.

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For both the Run In and Dose Expansion, the study periods and durations for participants are:
• Screening: ?28 days prior to apheresis
• Apheresis/Enrollment
• Bridging therapy: For participants who are at high risk to experience disease progression during the manufacture of JNJ-90009530 drug product and before lymphodepletion, a bridging therapy is allowed at the investigator’s discretion and Sponsor’s approval.
• Lymphodepletion: Day -5 to Day -3 (window to begin lymphodepletion: Day -7 to Day -5)
• JNJ-90009530 single infusion: Day 1
• Post-infusion follow-up: Beginning after JNJ-90009530 infusion (DLT period: Days 1 to 29) and continuing up to Day 90
• Post-treatment follow-up: Beginning after post-infusion follow-up and continuing 2 years postinfusion
• Long-term follow-up: beginning after post-treatment follow-up

Intervention Type

Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
JNJ-90009530

Primary outcome(s)
Current primary outcome measure as of 14/03/2025:

1. Occurrence of AEs and abnormal laboratory results, including dose limiting toxicities (DLTs) for up to 24 months
2. Determine Recommended Phase 2 dose (RP2D) with review of the number of dose-limiting toxicities for up to 24 months

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Previous primary outcome measure:

1. Occurrence of AEs and abnormal laboratory results, including dose limiting toxicities (DLTs) for up to 24 months

Key secondary outcome(s))
Current secondary outcome measures as of 14/03/2025:

1. Overall Response (OR), which includes Partial Response (PR) and Complete Response (CR) for up to 24 months
2. Time to response (TTR), defined as the time from the date of JNJ-90009530 infusion to the first documented CR or PR for up to 24 months
3. Duration of response (DOR), defined as the time from the first documented CR or PR to relapse or death (whichever occurs first) for up to 24 months
4. Amount of JNJ-90009530 in blood over time by measuring the Chimeric Antigen Receptor (CAR) copy number over time by Quantitative polymerase chain reaction (qPCR) for up to 24 months

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3. Duration of response (DOR), defined as the time from the first documented CR or PR to relapse or death (whichever occurs first) for up to 24 months
4. Amount of JNJ-90009530 in blood over time for up to 24 months

Completion date
03/01/2040

Eligibility

Key inclusion criteria
1. Participant must be greater than or equal to (>=) 18 years of age, at the time of signing informed consent
2. All participants must have relapsed or refractory disease for each histologic subtype-Mature aggressive large B cell NHL and Follicular Lymphoma Grade 3b: Participants must have >= 2 lines of systemic therapy or >=1 line of systemic therapy in case of participants ineligible for high-dose chemotherapy and autologous Hematopoietic stem cell transplantation (HSCT). Participants also must have had exposure to an anthracycline and an anti-CD20 targeted agent-Follicular lymphoma Grade 1-3a and Marginal Zone Lymphoma: Participants must have >=2 prior lines of anti-neoplastic systemic therapy. Participants also must have prior exposure to an anti-CD20 monoclonal antibody
3. Tumor must be cluster of differentiation (CD) 20 positive
4. Measurable disease as defined by Lugano 2014 classification
5. Eastern Cooperative Oncology Group (ECOG) performance status of either 0 or 1

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
150 years

Sex
All

Total final enrolment
20

Key exclusion criteria
1. Diagnosis of Human herpes virus (HHV) 8-positive Diffuse large B Cell lymphoma (DLBCL)
2. Prior allogeneic Hematopoietic stem cell transplantation (HSCT)
3. Autologous stem cell transplant within 12 weeks of chimeric antigen receptor (CAR) T cell infusion
4. Uncontrolled active infections
5. History of deep vein thrombosis or pulmonary embolism within six months of infusion (except for line associated deep vein thrombosis [DVT])
6. History of stroke, unstable angina, myocardial infarction, congestive heart failure (New York Heart Association [NYHA] Class III or IV), severe cardiomyopathy or ventricular arrhythmia requiring medication or mechanical control within 6 months of screening
7. History of a seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar

disease or neurodegenerative disorder
8. Known history or prior diagnosis of optic neuritis or other immunologic or inflammatory disease affecting the central nervous system
9. Active central nervous system (CNS) involvement by malignancy
10. Current active liver or biliary disease (except for Gilbert’s syndrome or asymptomatic gallstones)

Date of first enrolment
17/05/2024

Date of final enrolment
01/12/2025

Locations

Countries of recruitment
United Kingdom

Australia

Israel

United States of America

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
England
NW1 2PG

Sponsor information

Organisation
Janssen-Cilag International NV

Funder(s)

Funder type
Industry

Funder Name

Janssen Research & Development, LLC

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date, Not expected to be made available