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A study of JNJ-95804306 for relapsed or refractory hematological malignancies

Submission date
08/04/2026

Recruitment status
Recruiting

Registration date
15/06/2026

Overall study status
Ongoing

Last Edited
03/07/2026

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Hematological malignancies, also called blood cancers, develop when blood cells grow and divide abnormally. The specific cancer depends on which cell type is abnormal, and 4 examples of blood cancers are acute myeloid leukemia (AML), myelodysplastic syndromes (MDS), Chronic lymphocytic leukemia (CLL), and Small Lymphocytic Lymphoma (SLL), which can be, refractory* or relapsed**(R/R). As there are no approved or limited treatments for R/R disease, there is a need for better treatment options.
*do not respond to treatment
**cancer comes back

JNJ-95804306 works by targeting and breaking down a protein called B-cell lymphoma 2 which helps cancer cells survive. Targeting this protein helps to prevent cancer cell growth and leads to cell death.

In this study, researchers want to assess how safe JNJ-95804306 is and how well participants are able to tolerate it. Additionally, to identify the RP2D of JNJ-95804306 when given alone or in addition to SoC in participants with hematological malignancies.

Who can participate?
Participants aged 18 years or older with R/R AML/HR-MDS and R/R CLL/SLL.

What does the study involve?
Study consists of:
1. Screening Phase (within 30 days before first dose)

2. Treatment Phase (up to end of treatment [EOT; that is less than or equal to {<=} 30 days after last dose of study drug]): Participants will be divided into 2 arms.
• Arm A (R/R AML/HR-MDS): JNJ-95804306 alone (Arm A1) or in addition to AML SoC (Arm A2)
• Arm B (R/R CLL/SLL): JNJ-95804306 alone (Arm B1) or in addition to CLL/SLL SoC (Arm B2 or B3)

Each arm will consist of 2 parts:
• Part 1 (Dose Escalation): Determine the RP2D regimen(s)
• Part 2 (Dose Expansion): Assess for safety at RP2D

3. Post-treatment Follow-up Phase (up to 12 months after EOT)
Safety assessments include monitoring of adverse events, clinical laboratory tests, electrocardiogram (test to record heart activity), eastern cooperative oncology status (how well participants can take care of themselves) and vital signs. The overall duration of study will be up to 6 years 5 months.

What are the possible benefits and risks of participating?
Participants may not receive any benefit from taking part in this study, but the information that is learned from the study may help people with hematological malignancies (R/R AML/HR-MDS and R/R CLL/SLL) in the future.

This is a first-in-human study which means that JNJ-95804306 has not been given to people before.

The expected risks for JNJ-95804306, based on how the drug works and results from laboratory studies are listed below: large numbers of cancer cells dying rapidly causing metabolic imbalance (tumor lysis syndrome), lower-than-normal count of blood cells, including red cells, white blood cells and platelets (cytopenia), infections, harmful effects to embryo and fetus, harmful effects to stomach and intestine, liver, and heart. For participants receiving JNJ-95804306 in addition to SoC, there may be additional side effects related to the other therapies or the effects of the multiple drugs.

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-Cilag International NV.

When is the study starting and how long is it expected to run for?
May 2026 to September 2032.

Who is funding the study?
Janssen-Cilag International NV.

Who is the main contact?
RA-JanssenUKRegistry@ITS.JNJ.com

Contact information

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Scientific, Public

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Additional identifiers

Clinical Trials Information System (CTIS)
2026-525234-39

Integrated Research Application System (IRAS)
1013871

Central Portfolio Management System (CPMS)
73270

Sponsor's protocol code number
95804306EDI1001

Study information

Scientific Title
A phase 1, first-in-human, dose escalation study of JNJ-95804306 for relapsed or refractory hematological malignancies

Study objectives
Primary objectives:
Phase 1 (Dose Escalation): To assess how safe JNJ-95804306 is and how well participants are able to tolerate it. To identify the most suitable dose regimen (recommended phase 2 dose [RP2D]) of JNJ-95804306 when given alone or in addition to standard of care (SoC) in participants with hematological malignancies
Phase 2 (Dose Expansion): To further assess how safe JNJ-95804306 is at RP2D in the expansion cohort(s) when given alone and in addition to SoC

Secondary objectives:
1. To assess the process by which JNJ-95804306 gets absorbed, distributed in the body, and excreted (pharmacokinetics) when given alone or in addition to SoC
2. To assess the ability of JNJ-95804306 to slow down the growth or help shrink tumors (anti-tumor activity) when given alone or in addition to SoC in participants with hematological malignancies

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/05/2026, North West – Greater Manchester (GM) Central (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8084; gmcentral.rec@hra.nhs.uk), ref: 26/NW/0083

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Safety

Study type(s)

Health condition(s) or problem(s) studied
Hematologic neoplasms, blood cancer

Interventions
Arm A: R/R Acute Myeloid Leukaemia (AML)/ High-Risk Myelodysplastic Syndrome (HR MDS)
Participants with relapsed/refractory (R/R) AML/HR-MDS will receive JNJ-95804306 monotherapy (Arm A1) or as an addition to standard of care (SoC) therapy in AML (Arm A2) to determine the putative recommended phase 2 dose (RP2D) in Part 1 (Dose escalation) of the study.
In Part 2 (Dose expansion) participants will receive JNJ-95804306 monotherapy (Arm A1) or as an addition to SoC therapy in AML (Arm A2) at the determined RP2D regimen(s).
JNJ-95804306 will be administered orally.
AML SoC will be administered subcutaneously/intravenously

Arm B: R/R Chronic Lymphocytic Leukemia (CLL)/ Small Lymphocytic Lymphoma (SLL)
Participants with R/R CLL/SLL will receive JNJ-95804306 monotherapy (Arm B1) or as an addition to SoC therapy in CLL/SLL (Arm B2 or B3) to determine the putative RP2D in Part 1 (Dose escalation) of the study.
In Part 2 (Dose expansion) participants will receive JNJ-95804306 monotherapy (Arm B1) or as an addition to SoC therapy in CLL/SLL (Arm B2 or B3) at the determined RP2D regimen(s).
JNJ-95804306 will be administered orally.
CLL/SLL SoC will be administered orally/intravenously.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
JNJ-95804306

Primary outcome(s)
1. Part 1: Number of Participants with Dose Limiting Toxicities (DLTs)
A DLT is defined as any toxicity that requires discontinuation of treatment; any Grade 5 toxicity; Non-hematologic Toxicity (Grade 3 or 4); and unacceptable hematologic toxicity. Up to 21 days after first full dose of study drug
2. Number of Participants with Adverse Events (AEs) by Severity
An AE is any untoward medical occurrence in a participant administered a pharmaceutical (investigational or non investigational) product. An AE does not necessarily have a causal relationship with the treatment. Severity of AEs will be graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCICTCAE) version (v) 6.0. by using standard grades as follows: Grade 1: Mild; asymptomatic or mild symptoms; Grade 2: Moderate;

minimal, local or noninvasive intervention indicated; Grade 3: Severe but not immediately life threatening; hospitalization or prolongation of hospitalization indicated; Grade 4: Life-threatening consequences; and Grade 5: Death related to AE. Up to 6 years 5 months

Key secondary outcome(s)

Up to approximately 6 years 5 months
1. Serum Concentrations of JNJ-95804306
Serum samples will be analyzed to determine concentrations of JNJ-95804306.
2. Area Under the Curve From Time of Administration until End of Dosing Interval (AUC[t]) of JNJ-95804306
AUC[t] is defined as the area under the plasma concentration time curve during a dosing interval at steady-state.
3. Maximum Plasma Concentration (Cmax) of JNJ-95804306
Cmax is defined as the maximum serum concentration of JNJ-95804306.
4. Minimum Plasma Concentration (Cmin) of JNJ-95804306
Cmin is defined as the minimum plasma concentration of JNJ-95804306.
5. Complete Response (CR) in Participants with Acute Myeloid Leukemia (AML)
Complete response (CR) is achieved when a participant with AML has a best response of CR (complete response with partial hematologic recovery [CRh] or complete response with incomplete hematologic recovery [CRi]) according to the European Leukemia Network (ELN) 2022 criteria.
6. Overall Response (OR) in Participants with Myelodysplastic Syndrome (MDS)
OR is achieved when a participant with MDS has a CR (any type, that is CRh or complete response with limited count recovery [CRL]), partial response (PR), or hematologic improvement (HI) according to the International Working Group (IWG) 2023 criteria.
7. Complete Response (CR) in Participants with MDS
CR is achieved when a participant with MDS has a best response of CR (including CRh/CRL) according to the IWG
2023 criteria.
8. Overall Response (OR) in Participants with Chronic Lymphocytic Leukemia (CLL)
OR is achieved when a participant with CLL has a CR or PR according to the International Workshop on Chronic
Lymphocytic Leukemia (iwCLL) criteria.
9. Complete Response in Participants with CLL
Complete response as per iwCLL response criteria will be reported.
10. Overall Response in Participants with Small Lymphocytic Lymphoma (SLL)
Overall response in participants with SLL is achieved when a participant with SLL has a CR or PR according to the
revised response criteria for malignant lymphoma.
12. Complete Response in Participants with SLL
Complete response is achieved when a participant with SLL has a best response of CR according to the revised
response criteria for malignant lymphoma.
13. Duration of Response (DoR)
DOR is defined for responders only, as time from date of initial documentation of a response to the first documented evidence of no response, disease progression, relapse, initiation of a new systemic anti-cancer therapy (besides hematopoietic stem cell transplant [HSCT]), or death, whichever comes first.
14. Time to Response (TTR)
TTR is defined for responders only, as the time from the first dose of any study treatment to first qualifying response.

Completion date
24/09/2032

Eligibility

Key inclusion criteria
For Arm A:
1. Have a diagnosis of: Acute myeloid leukemia (AML) per International Consensus Classification (ICC) 2022 or myelodysplastic syndromes (MDS) per world health organization (WHO) 2022 classified as moderate high, high, or very high-risk per the molecular international prognostic scoring system (IPSSM). All participants must have relapsed or refractory disease and have exhausted or are ineligible for standard therapeutic options
2. Body weight greater than or equal to (>=) 40 kilograms (kg)
3. Eastern cooperative oncology group (ECOG) performance status of 0 to 2

For Arm B:
1. Have a diagnosis of chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) that meets international workshop on chronic lymphocytic leukemia (iwCLL), National cancer institute (NCI) Working
Group Guidelines which is relapsed or refractory and requires treatment with no other approved therapies available that would be more appropriate in the investigator's judgment.
1.1. Participants must have received at least 2 prior lines of therapy
1.2. Participants who have received at least one prior line of therapy but are not eligible or do not have access to standard second line therapies, will be allowed to enroll
2. Body weight >= 40 kg
3. ECOG performance status of 0 to 2
4. Have clinically measurable disease

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
For Arm A:
1. Has acute promyelocytic leukemia according to world health organization (WHO) 2016 criteria or known active central nervous system (CNS) involvement of AML/MDS, unless in specific

cohort (s) per study evaluation team (SET) decision
2. Need for supplemental oxygen use to maintain adequate oxygenation
3. Have evidence of uncontrolled systemic viral, bacterial, or fungal infection. Antimicrobial prophylaxis is permitted

For Arm B:
1. Need for supplemental oxygen use to maintain adequate oxygenation
2. Have evidence of uncontrolled systemic viral, bacterial, or fungal infection requiring initiation of parenteral treatment as medical intervention
3. Developed Richter's transformation or prolymphocytic leukemia
4. Known active CNS or leptomeningeal involvement of CLL/SLL

Date of first enrolment
14/05/2026

Date of final enrolment
01/05/2030

Locations

Countries of recruitment
United Kingdom

Australia

Belgium

Denmark

France

Germany

Spain

United States of America

Study participating centre
The Christie NHS Foundation Trust
550 Wilmslow Road
Withington
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Sponsor information

Organisation
Janssen-Cilag International NV

Funder(s)

Funder type

Funder Name
Janssen-Cilag International NV

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing policy of Johnson & Johnson Innovative Medicine is available at www.innovativemedicine.jnj.com/our-innovation/clinical-trials/transparency.
As noted on this site, requests for access to the study data can be submitted through Yale Open Data Access (YODA) Project site at yoda.yale.edu

IPD sharing plan summary
Available on request