ISRCTN87946208 https://doi.org/10.1186/ISRCTN87946208

A rollover study for continued study treatment and ongoing safety monitoring

Submission date 07/11/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 08/01/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 19/03/2025	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aim
Non-Hodgkin Lymphoma (NHL) and Chronic Lymphocytic Leukemia (CLL) are cancers that affect a certain type of white blood cells called lymphocytes.
The platform rollover study provides continued long-term access to following study treatment (s) for participants currently receiving the active study treatment and deriving benefit from it for the specified disease conditions:
- JNJ-64264681 [*64264681LYM1001]
- JNJ-67856633 (safimaltib) [*67856633LYM1001]
- JNJ-75348780 [*75348780LYM1001]
*Parent studies are adapted into Intervention Specific Appendix (ISA) within this platform study.
In this study, researchers want to evaluate the long-term safety of active study treatment and benefits from study treatment by providing long-term treatment access.

Who can participate?
Participants 18 years of age or older, diagnosed with NHL or CLL.

What does the study involve?
This study will be conducted as a continuous safety monitoring of the active study treatment for drugs (JNJ-64264681, JNJ-67856633 [safimaltib], and JNJ-75348780) administered in the parent studies.
Eligible participants in the parent study will rollover to this platform study. Participants from parent studies will sign an informed consent for this platform study, and initiate the platform study under the relevant ISA. Participants will continue to receive study treatment at the dose they received in the parent study and will be monitored for safety until progression of disease, or any discontinuation criteria is met as per relevant ISA.

What are the possible benefits and risks of participating?
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, longlasting, 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. While all of the participants in this study have benefited from their study therapies in the past, it is possible that these therapies will stop providing the previously observed benefits or that new toxicities arise.

Where is the study run from?
Janssen-Cilag International NV (Netherlands)

When is the study starting and how long is it expected to run for?
November 2024 to January 2028

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

Who is the main contact?
Ms Florence Baluwa, JanssenUKRegistryqueries@its.jnj.com

Contact information

Type(s)
Public

Contact name
Dr Vlad Melnyk

Contact details
50-100 Holmers Farm Way
High Wycombe
United Kingdom
HP12 4DP
-
JanssenUKRegistryQueries@its.jnj.com

Type(s)
Principal investigator

Contact name
Dr David Lewis

Contact details
Derriford Road
Plymouth
United Kingdom
PL6 8DH

Type(s)
Scientific

Contact name
Ms Florence Baluwa

Contact details
50-100 Holmers Farm Way
High Wycombe
United Kingdom
HP12 4DP
-
JanssenUKRegistryqueries@its.jnj.com

Additional identifiers

Clinical Trials Information System (CTIS)
2024-515457-21

Integrated Research Application System (IRAS)
1010963

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 65666

Study information

Scientific Title
PLATFORMPACAN1001: An open-label, rollover platform study for continued study treatment and ongoing safety monitoring

Acronym
PLATFORMPACAN1001

Study objectives
Primary objective:
To collect long-term continued safety monitoring data in participants with relapsed/refractory cancers including non-Hodgkin lymphoma (NHL) and chronic lymphocytic leukemia (CLL).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 06/01/2025, West Midlands - Edgbaston Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; edgbaston.rec@hra.nhs.uk), ref: 24/WM/0247

Study design
Interventional non randomized

Primary study design
Interventional

Study type(s)
Safety

Health condition(s) or problem(s) studied
Non-Hodgkin lymphoma and chronic lymphocytic leukemia

Interventions
The platform rollover study provides continued long-term access to study treatment(s) (JNJ-64264681; JNJ-67856633 (safimaltib); JNJ-54179060 (ibrutinib); JNJ-75348780; JNJ-74856665; JNJ-64619178; JNJ-70218902) for participants currently receiving the active study treatment in parent studies and deriving benefit from it. Eligible participants in parent study will rollover to this platform study which will be adapted into Intervention Specific Appendix (ISA) within the platform study. Participants will initiate the platform study under the relevant ISA, and will continue to receive study treatment at the dose they received in parent study.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
JNJ-64264681 [JNJ-64264681 DIHYDRATE] , JNJ-67856633 [SAFIMALTIB] , JNJ-75348780 [JNJ-75348780]

Primary outcome(s)
Number of Participants with Serious Adverse Events (SAEs) and Grage Greater than or equals to (>=) 3 Related Adverse Events (AEs). Timeframe: Up to approximately 3 years and 7 months. Description: An AE in any untoward medical occurrence in a clinical study participant administered a pharmaceutical (investigational or non-investigational) product. An AE does not necessarily have a causal relationship with the treatment. An SAE is any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect in the offspring of a study participant, is considered or defined as an important medical event, or abnormal pregnancy outcomes.

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
21/01/2028

Eligibility

Key inclusion criteria
1. Have participated in a parent study, with a linked intervention specific appendix (ISA) within this platform study, in which they initially received study treatment(s) prior to rolling over to this platform study
2. Satisfy all ISA specific inclusion criteria
3. Sign an informed consent form (ICF) (or their legally acceptable representative must sign) indicating that the participant understands the purpose of, and procedures required for, the study and is willing to participate in the platform study with details per the relevant ISA

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Have any condition or situation which, in the opinion of the investigator, may put the subject at significant risk, may confound the study results, or may interfere significantly with the subject' s participation in the study
2. Have unacceptable toxicities or overt disease progression observed at the time of rollover to the respective ISA
3. Meets any exclusion criteria within the pertinent ISA

Date of first enrolment
31/12/2024

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
United Kingdom

Belgium

France

Georgia

Greece

Israel

Japan

Poland

Taiwan

Ukraine

Study participating centre
-
United Kingdom
-

Sponsor information

Organisation
Janssen-Cilag International NV

Funder(s)

Funder type
Industry

Funder Name
Janssen Research and Development

Alternative Name(s)
Janssen R&D, Janssen Research & Development, Janssen Research & Development, LLC, Janssen Research & Development LLC, Janssen Pharmaceutical Companies of Johnson & Johnson, Research & Development at Janssen, JRD, J&J PRD

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing policy of the Janssen Pharmaceutical Companies of Johnson and Johnson is available at www.janssen.com/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