# A long-term extension study of JNJ-81201887 (AAVCAGsCD59) parent studies in participants with geographic atrophy (GA) secondary to agerelated macular degeneration (AMD)

Submission date 10/09/2024	Recruitment status Recruiting	Prospectively registered
		☐ Protocol
Registration date	Overall study status	Statistical analysis plan
11/02/2025	Ongoing	Results
Last Edited	<b>Condition category</b> Eye Diseases	Individual participant data
11/02/2025		[X] Record updated in last year

# Plain English summary of protocol

Background and study aims

Age-related macular degeneration (AMD) is an eye disease that can lead to vision loss. It happens when aging causes the central part of the vision to become blurry or dark due to damage to a part of the eye called the macula. Geographic atrophy (GA) is an advanced form of AMD that leads to progressive and permanent loss of vision. JNJ-81201887 is a gene therapy that increases the ability of the retina cells to make CD59\* which may help prevent further damage to the retina and preserve vision. In this long-term extension (LTE) study, researchers want to learn about the long-term safety and explore how well participants can tolerate (tolerability) JNJ81201887 when given as an injection into the eye during parent clinical studies (81201887MDG2001, 81201887MDG1003).

\* Protein that protects retina from damage caused by an essential part of the body's natural immune response called the complement system.

Participants with GA who were enrolled and received treatment with JNJ-81201887 or sham\* in the parent studies.

# Who can participate?

No study intervention will be administered to the participants in this LTE study. Adult participants who were enrolled and treated with JNJ-81201887 or sham in the parent clinical studies will be enrolled and followed up for safety in this LTE study.

## What does the study involve?

Participants who received sham in the parent study (81201887MDG2001) may have the option to receive JNJ-81201887 as an open-label treatment\* under a separate study and will be followed-up for 5 years from time of administration of JNJ-81201887 in parent clinical studies. \*Both researchers and participants knew about the drug or treatment being given. Participants will undergo study assessments such as eye tests, eye imaging scans, physical examination, monitoring of side effects, questionnaires and blood tests. All side effects will be

<sup>\*</sup>An inactive procedure designed to mimic the active procedure.

recorded till the study ends (up to approximately 5 years from time of administration of JNJ-81201887).

What are the possible benefits and risks of participating?

There is no established benefit to participants of this study. Based on scientific theory, receiving JNJ-81201887 may slow the progression of Geographic Atrophy (GA) secondary to Age-related Macular Degeneration (AMD). However, this cannot be guaranteed because JNJ-81201887 is still under investigation as a treatment and it is not known whether JNJ-81201887 will work. Participants may experience some benefit from participation in the study that is not due to receiving study drug, but due to regular visits and assessments monitoring overall health. Participation may help other people with GA secondary to AMD in the future.

Participants may have side effects from the drugs or procedures used in the parent clinical studies that may be mild to severe, and they can vary from person to person. The most common known risks are getting symptoms such as inflammation inside the eyes.

The participant information sheet and informed consent form, which will be signed by every participant agreeing to participate in the study, includes a detailed section outlining the known risks of participating in the study.

Not all possible side effects and risks related to JNJ-81201887 are known at this moment. During the study, the sponsor may learn new information about JNJ-81201887. The study doctor will tell participants as soon as possible about any new information that might make them change their mind about being in the study, such as new risks.

To minimise the risk associated with taking part in the study, participants are frequently reviewed for any side effects and other medical events. Participants are educated to report any adverse events to the study doctor who will provide appropriate medical care. Any serious side effects that are reported to the sponsor are thoroughly reviewed by a specialist drug safety team.

There are no costs to participants to be in the study. The participant will receive reasonable reimbursement for study-related costs (e.g., travel/parking costs).

Where is the study run from? Janssen-Cilag International N.V.

When is the study starting and how long is it expected to run for? September 2024 to August 2029

Who is funding the study? Janssen-Cilag International N.V.

Who is the main contact? Participate-In-This-Study@its.jnj.com

# **Contact information**

Type(s)
Scientific

Contact name

Mrs Lorraine Smith

Contact details

50-100 Holmers Farm Way High Wycombe United Kingdom HP12 4DP

# Type(s)

Principal investigator

## Contact name

Prof Paulo Stanga

## Contact details

24 Queen Anne Street London United Kingdom W1G 7LB

# Additional identifiers

Clinical Trials Information System (CTIS)

2022-500747-21

**Integrated Research Application System (IRAS)** 

1010481

ClinicalTrials.gov (NCT)

NCT06635148

Protocol serial number

81201887MDG3002

# Study information

## Scientific Title

Long-term extension study for participants with geographic atrophy (GA) secondary to agerelated macular degeneration (AMD) in JNJ-81201887 parent clinical studies

# **Acronym**

JNJ-18201887 LTE

# Study objectives

Primary objective:

To assess the long-term safety and how well participants can tolerate (tolerability) JNJ-81201887, when given as an injection into the eye in parent clinical studies (81201887MDG2001, 81201887MDG1003).

# Ethics approval required

Ethics approval required

Ethics approval(s)

approved 07/11/2024, West London & GTAC Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8184; westlondon.rec@hra.nhs.uk), ref: 24/LO/0580

# Study design

Interventional non-randomized long-term extension study

## Primary study design

Interventional

# Study type(s)

Safety, Efficacy

# Health condition(s) or problem(s) studied

Geographic Atrophy, secondary to age-related macular degeneration

### **Interventions**

Study participants who were enrolled and received treatment with low dose JNJ-81201887 in parent clinical studies (81201887MDG2001 [NCT05811351]; 81201887MDG1003) will enter this long-term extension (LTE) study. No study intervention will be administered as part of this study.

Study participants who were enrolled and received treatment with high dose JNJ-81201887 in parent clinical studies (81201887MDG2001 [NCT05811351]; 81201887MDG1003) will enter this LTE study. No study intervention will be administered as part of this study.

Participants randomised to the sham arm in parent study 81201887MDG2001 (NCT05811351) may have the option to receive JNJ-81201887 open-label treatment under a separate protocol after unmasking that study and will enter this LTE study. No intervention will be administered as part of this study.

# Intervention Type

Drug

#### Phase

Phase II

# Drug/device/biological/vaccine name(s)

AAVCAGsCD59, prednisone

## Primary outcome(s)

- 1. The number of participants with ocular and systemic TEAEs will be reported. An adverse event (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. TEAEs are defined as any adverse event occurring at or after the administration of study intervention, up to 5 years
- 2. The number of participants with abnormal findings in clinical laboratory Assessments (including hematology and clinical chemistry) will be reported, up to 5 years
- 3. The number of participants with abnormal findings in retinal imaging (Fundus Autofluorescence, Spectral Domain Optical Coherence Tomography, Color Fundus Photography) and eye examinations will be reported, up to 5 years

# Key secondary outcome(s))

There are no secondary outcome measures

# Completion date

29/08/2029

# **Eligibility**

## Key inclusion criteria

- 1. Participants who were enrolled and received treatment with JNJ-81201887 or sham in a parent clinical study (81201887MDG2001, 81201887MDG1003)
- 2. Females (women of childbearing potential), male participants, and partners of male participants will not be required to use contraception in this LTE study
- 3. Must sign an informed consent form (ICF) indicating that participant understands the purpose of, and procedures required for, the study and is willing to participate in the study. The ICF may be signed by an impartial witness and/or legally designated representative depending on national/local regulations

# Participant type(s)

Patient

# Healthy volunteers allowed

No

# Age group

Adult

## Sex

All

## Key exclusion criteria

There are no exclusion criteria for this LTE study

## Date of first enrolment

19/09/2024

## Date of final enrolment

26/02/2026

# Locations

## Countries of recruitment

United Kingdom

Australia

Belgium

Canada

Netherlands
Poland
Portugal
Spain
Sweden
Switzerland
Türkiye
United States of America
Study participating centre
- United Kingdom
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Sponsor information

Janssen-Cilag International N.V.

Czech Republic

Denmark

Germany

Hungary

Italy

# Funder(s)

Organisation

**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 datasets generated during and/or analysed during the current study are/will be available upon request from (please provide the name and email address, the type of data that will be shared, when the data will become available and for how long, by what access criteria data will be shared including with whom, for what types of analyses, and by what mechanism, whether consent from participants was obtained, comments on data anonymisation, any ethical or legal restrictions, any other comments). The data sharing policy of the Janssen Pharmaceutical Companies of Johnson & 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

# Study outputs

Output type Date created Date added Peer reviewed? Patient-facing? Details Participant information sheet 11/11/2025 No Participant information sheet

Yes