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

Submission date 10/09/2024	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 11/02/2025	**Overall study status** Ongoing	[ ] Statistical analysis plan [ ] Results
Last Edited 11/02/2025	**Condition category** Eye Diseases	[ ] Individual participant data [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.
*An inactive procedure designed to mimic the active procedure.

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

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

EudraCT/CTIS number
2022-500747-21

IRAS number
1010481

ClinicalTrials.gov number
NCT06635148

Secondary identifying numbers
81201887MDG3002

Study information

Scientific Title
Long-term extension study for participants with geographic atrophy (GA) secondary to age-related 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

Secondary study design
Non randomised study

Study setting(s)
Hospital, Other therapist office

Study type(s)
Safety, Efficacy

Participant information sheet
No participant information sheet available

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

Pharmaceutical study type(s)
Pharmacodynamic, Therapy, Others (Biodistribution/shedding and immunogenicity)

Phase
Phase II

Drug/device/biological/vaccine name(s)
AAVCAGsCD59, prednisone

Primary outcome measure
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

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
05/09/2024

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

Age group
Adult

Sex
Both

Target number of participants
311

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
Australia

Belgium

Canada

Czech Republic

Denmark

Germany

Hungary

Italy

Netherlands

Poland

Portugal

Spain

Sweden

Switzerland

Türkiye

United Kingdom

United States of America

Study participating centre
-
United Kingdom
-

Sponsor information

Organisation
Janssen-Cilag International N.V.

Sponsor details
Archimedesweg 29
Leiden
Netherlands
2333 CM
+31 71 5242166
ClinicalTrialsEU@its.jnj.com

Sponsor type
Industry

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

Publication and dissemination plan
1. Peer-reviewed scientific journals
2. Internal report
3. Publication on website
4. Submission to regulatory authorities

Study results will be available via publication in scientific journals, the EudraCT and ISRCTN databases & presentation at scientific meetings. Results will be made available to participants via a Plain Language Summary a year after the end of the study.
The summary will describe the results regardless of study outcome in language that is understandable to the general public. It will not contain individual participant results or their personal information. A copy of the Summary will be provided to the REC.

Intention to publish date
29/08/2030

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