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A study to evaluate the long-term safety and tolerability of faricimab administered in patients previously enrolled in Roche-sponsored studies

Submission date
12/07/2021

Recruitment status
No longer recruiting

Registration date
06/08/2021

Overall study status
Completed

Last Edited
05/12/2023

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims:
The purpose of this study is to assess long-term safety of faricimab therapy and provide access to continued treatment with faricimab, as applicable, to patients with Diabetic Macular Edema (DME), Neovascular Age-related Macular Degeneration (nAMD), or Retinal Vein Occlusion (RVO).

Faricimab is an experimental drug, which means health authorities have not approved it for the treatment of DME, nAMD, or RVO outside of a clinical study. As of November 2020, more than 3,350 patients have been enrolled in either the completed or ongoing clinical studies of faricimab in patients with DME and nAMD. Of these patients, more than 2,100 patients have received at least one dose of faricimab.

Who can participate?
Patients who were previously enrolled in the mainland of China and completed any of Roche-sponsored faricimab parent trials

What does the study involve?
Participants will be placed in a single treatment group:
Participants will receive faricimab 6 mg injections into the study eye at a variable interval depending on the condition of their eye. Frequency of injections will be determined by the study doctor, usually varying between every 4 weeks and every 16 weeks.
Participants will only be required to attend the clinic according to the study doctor’s discretion, but the interval between visits should be no more than 4 months and no less than 21 days.

What are the possible benefits and risks of participating?
Your health may or may not improve in this study, but the information that is learned may help other people who have a similar medical condition in the future.
You may have side effects from the drugs or procedures used in this study. Side effects can be mild to severe and even life threatening, and they can vary from person to person. There may be

a risk in exposing an unborn child to the study drug, and all risks are not known at this time. Women and men must take precautions to avoid exposing an unborn child to the study drug.

Where is the study run from?
Shanghai General Hospital (China)

When is the study starting and how long is it expected to run for?
August 2020 to August 2025

Who is funding the study?
F. Hoffmann-La Roche Ltd (Switzerland)
Genentech Inc (USA)

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
YR42837

Study information

Scientific Title
An open-label, multicenter extension study to evaluate the long-term safety and tolerability of faricimab administered in patients previously enrolled in studies sponsored by F. Hoffmann-La Roche Ltd

Study objectives
To investigate the long-term safety and tolerability of faricimab administered in patients previously enrolled in Roche-sponsored studies

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 05/03/2021, Shanghai General Hospital Institutional Review Board (No. 100, Haining Road, Shanghai, 200080, China; +86-21-36123569; Shiyilunli@sina.com), ref: [2021]026

Primary study design
Interventional

Study design
Non-randomized open-label multicenter standalone extension study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Macular degeneration

Interventions
Participants will be placed in a single treatment group:
Participants will receive faricimab 6 mg injections into the study eye at a variable interval depending on the condition of their eye. Frequency of injections will be determined by the study doctor, usually varying between every 4 weeks and every 16 weeks.
Participants will only be required to attend the clinic according to the study doctor’s discretion, but the interval between visits should be no more than 4 months and no less than 21 days.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Faricimab (RO6867461)

Primary outcome(s)
1. Eye condition measured using BCVA, pre-treatment IOP, slit-lamp examination, and Indirect ophthalmoscopy measured at baseline (Day 1) and each visit which is in the range of 21 days to 4 months
2. Effect of drug measured using finger-counting test and IOP (post-study treatment) are measured after each administration. As the study drug administration has no mandatory timepoint and is decided by the clinical judgment of the investigator, these assessments have no specified timepoint
3. Other eye tests, SD-OCT, CFP, and FFA are also measured according to the investigator's discretion, they have no specified timepoint

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

Completion date
04/08/2025

Eligibility

Key inclusion criteria
1. Previous enrollment in and completion of any faricimab parent study without study or study drug discontinuation.
2. Enrolled in the mainland of China
3. Signed Informed Consent Form
4. Ability and willingness to comply with the study protocol, in the investigator's judgment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Pregnant or breastfeeding, or intending to become pregnant during the study or within 28 days after the final ITV injection of faricimab
2. Women of childbearing potential must have a negative urine pregnancy test result within 28 days prior to initiation of study treatment. If the urine pregnancy test is positive, it must be confirmed by a serum pregnancy test.

Date of first enrolment
19/07/2021

Date of final enrolment
04/04/2025

Locations

Countries of recruitment
China

Study participating centre
Shanghai General Hospital
Shanghai
China
201620

Sponsor information

Organisation
F. Hoffman-la Roche

Funder(s)

Funder type
Industry

Funder Name
Genentech

Alternative Name(s)
Genentech, Inc., Genentech USA, Inc., Genentech USA

Funding Body Type
Government 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 not expected to be made available due to there being no regulatory requirement to do so.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes