19th March 2026

Dear members of the FSHD community,

Following your request for updates about our FSHD clinical development programme, today I share the news that we have made the difficult decision not to advance emugrobart (an investigational anti-myostatin antibody, also known as GYM329) into Phase III development in FSHD.

The decision to stop clinical activities for emugrobart in FSHD follows a rigorous assessment of the data from the MANOEUVRE (NCT05548556) clinical study – a Phase II trial designed to evaluate the safety, efficacy, tolerability, pharmacokinetics and pharmacodynamics of emugrobart, in people aged 18-65 years with FSHD. Unfortunately, emugrobart did not consistently deliver the hoped for improvements in muscle growth and function in people living with FSHD. This decision was not the result of any safety findings.

We recognise the significance of this decision for all who live with or care for someone living with FSHD and we understand that discontinuing emugrobart in FSHD is disappointing.

We are profoundly grateful to the study participants, their care partners, and study sites for their contributions to this important research. We would also like to thank the FSHD community for their partnership and expertise throughout the development of emugrobart in FSHD. We plan to share the data from MANOEUVRE at an upcoming medical conference so that this research can also help to inform the development of future treatments in FSHD.

If you have any questions about the information provided, please do not hesitate to reach out.

Sincerely,

Louisa Danielle Townson

Louisa Townson, on behalf of the Roche Global FSHD Team
Global Patient Partnership

Frequently Asked Questions

What did the Phase II MANOEUVRE study investigate?

- The Phase II MANOEUVRE clinical study was designed to evaluate the safety, efficacy, tolerability, pharmacokinetics and pharmacodynamics of emugrobart, an investigational anti-myostatin antibody, for the treatment of people aged 18-65 years with FSHD.

Why has the MANOEUVRE study been discontinued? Is it due to safety concerns?

- The Phase II MANOEUVRE study has not been discontinued due to any safety findings; emugrobart was well tolerated, with no serious adverse events or treatment withdrawals.
- The Phase II MANOEUVRE study has been discontinued following rigorous analysis of results which showed that emugrobart did not consistently deliver improvements in motor function compared to placebo.

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What will happen to participants who were involved in the MANOEUVRE trial?

- If you are a participant of MANOEUVRE, we encourage you to reach out to your study physician for more information and detailed next steps.
- We are working with study doctors to ensure a smooth and safe transition - this will involve discontinuation of emugrobart and safety follow-up assessments.
- We recognise the valuable contribution participants made to advancing medical science and while this decision was not made lightly, we will ensure it is handled with care and responsibility.

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