



20 February 2026

## Update on the investigation of satralizumab for bone health and the SHIELD DMD study

Dear Duchenne patient organisation leaders,

Today we share an important update regarding our work in **bone health in Duchenne**. At Roche, we routinely evaluate our portfolio to focus on delivering transformative medicines that address critical gaps in care. There are times when our assessment results in difficult decisions that affect an ongoing clinical study. These decisions are never taken lightly and are made with thoughtful consideration, guided by a systematic evaluative framework. We recognise that these decisions are never easy because they impact people.

We believe it is our responsibility to promptly communicate about decisions, as well as work with investigators and patient communities to minimise the impact and provide appropriate support.

Following a comprehensive review, we have made the decision to stop recruitment for the Phase II SHIELD DMD study ([NCT06450639](#), BN45398). The study will continue until the interim data collection point (six-month bone mineral density data), which is expected in the second half of 2026. After that, the study and further development of satralizumab for bone health in Duchenne will close. Data from the interim analysis will be shared with the community at a future medical conference.

These decisions were reached following careful consideration of the programme and in light of new information - including the feasibility of meeting regulatory requirements as well as recruitment and study completion timelines for SHIELD DMD and any future Phase III trials. These combined factors mean we no longer see a viable path forward for development. Without a realistic path to approval, continuing the study for longer would place an undue burden on trial families, sites and the broader community.

### Important to note

- **Not a safety issue:** This decision was not the result of any new efficacy data, new or unanticipated safety risks, or quality reasons.
- **No impact to other uses/studies of satralizumab:** This decision is related to research in bone health in Duchenne. The decision does not impact the use of satralizumab in other disease areas in which it has regulatory approval or is in development or registration.

### Communication to study sites and families

We are communicating with health authorities and investigators about this closure, transition plans, and support for sites and participants. SHIELD DMD has less than 30 participants enrolled and our priority is supporting transition for them and those in the screening process. Earlier this

week, SHIELD DMD sites were notified so they could contact trial families directly to provide information and discuss individual considerations, including:

- Participants enrolled in SHIELD DMD may choose to continue in the study until the six-month milestone on bone mineral density data is reached.
- People currently in screening who meet eligibility criteria may still choose to participate in the study until the six-month milestone.
- As with any of our studies, participants may choose to withdraw participation at any time.

Because SHIELD DMD is running in multiple countries (Denmark, Italy, Poland, Spain, Ukraine and USA), we acknowledge that families may have received news about the study at different times and in different channels.

While we will not be advancing satralizumab in bone health, we are committed to sharing the interim study data with the research and family communities to help advance the understanding of Duchenne. We are profoundly grateful to all patients, families, healthcare providers, study sites and research partners who contributed to this research.

Sincerely on behalf of the Roche Duchenne bone health team,

A handwritten signature in black ink that reads "Mai-Lise Nguyen". The signature is written in a cursive, flowing style.

Mai-Lise Nguyen  
Global Patient Partnership Leader