



## FALKON Study Termination

9<sup>th</sup> January 2026

Dear FOP Community,

Ipsen has reviewed the results of the primary analysis from the FALKON Part A study. Unfortunately, the study did not meet its primary endpoint (measured by heterotopic ossification volume reduction), nor show efficacy with key secondary endpoints (measured by new lesions, flare-ups and pain) compared to placebo. **Based on these definitive results and the totality of data available, we have made the decision to end the FALKON study.**

### Why is the study ending?

FALKON is the first clinical study to evaluate efficacy and safety of fidrisertib for patients living with FOP. Despite promising preclinical lab results, efficacy and safety must be demonstrated in patients for a clinical study to meet required objectives. As part of routine study conduct, discontinuation rules were part of the protocol to minimize exposing participants to treatments that may be unsafe or ineffective. During the study, an independent data monitoring committee analyzed the unblinded safety data on a quarterly basis and no safety signals were identified. However, as relates to efficacy (the measurement of how well a drug works), a futility rule was put in place at the Month 12 timepoint to discontinue the study if: 1) data failed to show a meaningful benefit compared to placebo; and 2) the study drug was unlikely to demonstrate a positive benefit by the end of the study.

The study unfortunately achieved a less than 20% reduction in heterotopic ossification volume reduction with treatment compared to placebo. The study also did not show a meaningful reduction of flare-up events and pain compared to placebo. This information was reviewed with the Data Monitoring Committee, which included two FOP experts, who endorsed the decision to terminate the study. It is important to state that the treatment was generally well tolerated, and no new or unexpected safety concerns were identified. However, this does not permit a study to continue as additional efficacy data from study continuation will not demonstrate a favourable benefit.

### May I choose to continue to take the study drug after the trial?

We truly appreciate the time, commitment and trust you placed in this study, and we understand how important this question is—especially given your personal experience during the trial.

Based on the analysis of the study results from all participants, fidrisertib did not show clear scientific evidence of benefit for people living with FOP. Because of this, and in line with our ethical and regulatory responsibilities, we cannot continue providing fidrisertib after the study is ended or make it available through an expanded access program.

We recognize that individuals can experience treatments differently, and we respect that you may have felt improvement while participating in the study. However, decisions about continued



access must be based on the overall study outcomes and the predefined measures used to assess benefit and risk across all participants.

We understand that this may be disappointing news, and we are sincerely grateful for your contribution to advancing FOP research. We encourage you to discuss your experience and any next steps with your treating physician, who can help explore other appropriate care or research options.

#### **Where can I find the full results?**

Ipsen will continue to analyse the unblinded study data to learn all we can, and we are committed to share the data with the community in a manuscript at a later date. Your study doctor can guide you to information that is publicly available now and to any future scientific publications or summaries once they are released.

#### **What happens next?**

On 19 December 2025, we disclosed this information via a [press release](#) and direct outreach to all FALKON study sites. As a next step, all study participants should engage directly with their study site and direct individual medical questions to their treating physician. If you have not yet heard from your site, we encourage you to reach out.

*Please note all FALKON study sites also received patient communication from Ipsen in December. Study sites are required to follow their institution's review processes prior to distribution. Distribution times will vary by institution.*

#### **Who can I go to with questions?**

If you have further questions, please do not hesitate to consult your treating physician. Your doctor can guide you to information that is publicly available now and to any future scientific publications or summaries once they are released.

The FALKON study was a tremendous undertaking for both Ipsen and the FOP community. It spanned six years of development, with 113 participants across 34 sites in 14 countries. **We'd like to acknowledge and thank the study patients and their families, as well as the healthcare professionals who participated in FALKON.** While the outcome of this study is not what we hoped for, your role has been critical to advancing potential treatments for FOP. The decision to stop the study does not diminish our gratitude for your contribution, nor our recognition of how challenging FOP is for those living with it and their families.

Sincerely,

A handwritten signature in black ink, appearing to read "Fei Shih".

**Fei Shih, MD PhD, Asset lead, fidrisertib**

If you have any additional enquiries, please contact [globalmedinfo@ipsen.com](mailto:globalmedinfo@ipsen.com)