



FALKON Study Update

December 19, 2025

Dear IFOPA and FOP Community,

We regret to inform you that the Phase II FALKON trial was not able to demonstrate a reduction in the volume of new abnormal bone growth (heterotopic ossification (HO)) in patients treated with fidrisertib compared to placebo ([Ipsen press release](#)). FALKON is not being terminated due to safety concerns.

We appreciate the commitment that participating in a clinical study involves and we are truly grateful to the individuals, families and healthcare professionals who participated in FALKON.

While this outcome is truly disappointing, we will take time to thoroughly review the data to be able to share learnings with the scientific and medical community, and to determine our next steps, so that other researchers can learn from the insights gained through this process.

We will share what we have learned at a medical congress, so that other companies and organizations with ongoing research programs can learn from the insights gained through this process.

Our journey in FOP has been long, and we will carefully consider our next steps. We would like to thank the patients who participated in the FALKON study. For those who participated in FALKON, the study site staff will be in touch to talk about next steps. We are deeply grateful to the FOP community for your trust, partnership and unwavering resilience.