Press Release

Ipsen update on Phase II FALKON trial in patients with ultra-rare bone disease, fibrodysplasia ossificans progressiva (FOP)

PARIS, FRANCE, 19 December 2025 – Ipsen (Euronext: IPN; ADR: IPSEY) today announced that the pivotal Phase II FALKON trial did not meet its primary endpoint of reducing new heterotopic ossification (HO) in adults and children living with fibrodysplasia ossificans progressiva (FOP) vs. placebo, as a result the study will be closed. The investigational medicinal product (fidrisertib) was generally well tolerated, with no safety concerns in the trial.

"These results are disappointing for the FOP community and patients living with this devastating disease," said Christelle Huguet, PhD, EVP, Head of Research and Development. "However, we do believe that these data will contribute to the growing body of research on FOP, giving new insights into managing this disease for patients and their care providers. FALKON was a tremendous undertaking by Ipsen, continuing our commitment to FOP. FALKON enrolled 113 patients globally, taking over 5 years to reach this critical milestone. We would like to thank the patients, caregivers, the FOP community and KOLs who dedicated their time to the FALKON trial, it has been a serious commitment to help advance our understanding of FOP."

About FOP

FOP is a genetic condition caused by pathogenic variants of the ALK2 kinase that leads to bone formation in soft and connective tissues, like muscles, tendons and ligaments, a process known as HO. Once formed, HO is irreversible. There are limited treatment options for patients with FOP. The average/median age of diagnosis is 5 years old and ultimately FOP shortens the life expectancy to a median of 56 years, with untimely death caused by bone formation around the ribcage, leading to breathing problems and thoracic insufficiency. FOP has an estimated prevalence of 1.36 per million individuals and approximately 900 people are diagnosed worldwide; however, the number of confirmed cases varies by country.

About fidrisertib

Fidrisertib is an oral, highly selective and potent small molecule inhibitor of pathogenic variants of the ALK2 kinase, the underlying root cause of FOP. Fidrisertib has been designed to address the unliganded ALK2 signal as well as BMP and aberrant activin liganded signal during flare up; impacting both flare-up based and non-flare-up based HO formation. Fidrisertib is administered orally (capsule sprinkled on food or dissolved in water) without change in dose during flare-ups.

About the FALKON Trial

FALKON is the largest Phase II trial in FOP, comprising 3 parts, designed to evaluate the efficacy, safety and tolerability of fidrisertib, as a first-line treatment in pediatric and adult patients with FOP. Part A is a global, multi-center, placebo-controlled, parallel-group, 3-arm trial, in which 113 patients aged 5 years

of age or older with the R206H ACVR1 mutation or other FOP variants associated with progressive HO, were enrolled and randomized to receive either high dose-weight based or low dose weight-based fidrisertib or placebo. The primary endpoint is annualized change from baseline in HO volume. In Part B of the double-blind trial, patients continue their dose of fidrisertib, with the patients on placebo in Part A also randomized to receive either high or low dose fidrisertib. Part C is an extension period for all patients who are responding.

About Ipsen

We are a global biopharmaceutical company with a focus on bringing transformative medicines to patients in three therapeutic areas: Oncology, Rare Disease and Neuroscience. Our pipeline is fueled by internal and external innovation and supported by nearly 100 years of development experience and global hubs in the U.S., France and the U.K. Our teams in more than 40 countries and our partnerships around the world enable us to bring medicines to patients in more than 100 countries.

Ipsen is listed in Paris (Euronext: IPN) and in the U.S. through a Sponsored Level I American Depositary Receipt program (ADR: IPSEY). For more information, visit ipsen.com.

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