Letter to FOP community regarding the EC decision not to grant marketing authorization approval to Palovarotene as a treatment for FOP

Dear FOP Community

It is with great disappointment that we have heard that the European Commission (EC) has determined not to grant marketing authorization approval for investigational palovarotene as a treatment for FOP.

This decision follows a negative opinion received by Ipsen in May this year, provided by the Committee for Medicinal Products for Human use (CHMP), a body that assesses applications and makes recommendations to the European regulatory authority. The EC often follows the guidance of the CHMP, therefore while this decision is not a surprise, it is still difficult to comprehend.

The team here at Ipsen has worked relentlessly and with determination to bring palovarotene to people living with FOP, knowing the need for an innovative treatment to reduce new heterotopic ossification. Following the negative CHMP opinion for palovarotene, received in January 2023, Ipsen made a subsequent request for re-examination of the data, requested an approval under exceptional circumstances and provided additional data and analysis from the existing clinical trial program, with a requested review by a scientific advisory group.

We have continued to be encouraged and humbled by the ongoing and enthusiastic support of the FOP community, who provided numerous testimonials to the CHMP, on the impact of the disease on those living with FOP and their families. In addition, to the expert healthcare providers, who manage the care of those with FOP, who gave evidence in support of the need for a treatment for this condition.

However, despite all of our best joint efforts, this final decision from the EC means that palovarotene will not be made available to patients with FOP living in the European Union.

We appreciate it is no consolation to those living in the E.U. that in June this year an advisory committee to the U.S. regulatory authority, the FDA, voted strongly in favor that evidence from the Phase III MOVE study show palovarotene is an effective treatment in patients with FOP. Also that the benefits of palovarotene outweigh the risks, for the treatment of patients with FOP. The final decision from the FDA will be received by 16 August 2023.

On behalf of all of the many people who have been working on the development of palovarotene over the years, I want to sincerely thank you, the FOP community, for your unwavering support. For your strength, hope, courage and resilience Your involvement in clinical trials and in activities to give insight and understanding has been invaluable. You are our motivation and drive to deliver on our ambition to bring a treatment for FOP to those living in the E.U.

Sincerely,

David Loew, CEO Ipsen