March 26, 2020

Dear FOP community,

We are pleased to share an important update regarding the palovarotene clinical trial in FOP. Following an extensive review of the efficacy and safety data from the Phase III MOVE clinical trial, Ipsen has announced it will reinitiate palovarotene dosing in patients 14 years of age and older who are currently enrolled in the study. (Click here to read the full news release).

The U.S. Food and Drug Administration (FDA) has confirmed they have no safety concerns with restarting dosing in patients 14 years of age and older. Clearance to reinitiate dosing in these patients has also been received from the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK, the National Agency for the Safety of Medicines and Health Products Safety (ANSM) in France, the Medical Products Agency (MPA) in Sweden, the Italian Medicines Agency (AIFA), the National Administration of Drugs, Foods, and Medical Devices (ANMAT) in Argentina, the Spanish Agency of Medicines and Medical Devices (AEMPS), and Health Canada (HC).

Once we receive approval from the ethics committee for each clinical trial site, the re-initiation of dosing may begin. When this happens, physicians or trial coordinators will contact eligible patients to share more details and advise on appropriate next steps for reinitiating treatment. Appropriate measures will also be taken to ensure the safety of FOP patients who restart dosing in light of the ongoing COVID-19 pandemic, taking into consideration local regulatory and health authority guidance, as well as the ability of individual investigators and sites to adequately monitor patient safety.

We also wanted to give an update on the partial clinical hold for patients under the age of 14. Ipsen is currently addressing the questions from the FDA and other health authorities to expeditiously establish a course of action for FOP studies for the pediatric population under the age of 14. We remain in regular contact with the clinical trial sites to ensure the investigators have the information needed for their communications with these study participants and their families.

We are incredibly grateful for the ongoing support provided by the FOP community – we couldn't do this without you. Every day poses challenges for those living with FOP and we understand the urgency in searching for a treatment. We hope this news moves us closer to developing therapeutic treatment options for people living with FOP.

Sincerely,

Dr. Howard Mayer
Executive Vice President and Head of Research and Development

Dr. Jim Roach
Senior Vice President and Global Head, Rare Diseases Therapeutic Area