January 24, 2020

Dear Members of the FOP Community,

We are writing to share that the Independent Data Monitoring Committee (IDMC) has informed us that our Phase III palovarotene clinical trial in FOP (MOVE trial) has reached the pre-specified interim analysis futility criteria, meaning that this trial is unlikely to reach the primary efficacy endpoint. While this is not the result we had hoped for, we have seen some encouraging signals of therapeutic activity based on additional analyses that have been shared with the IDMC. Click here to read the full news release for further information.

We are pausing dosing in the trials while we conduct further assessment of the complete data set. Our goal is to understand the implications of these signals of therapeutic activity to inform discussions with regulatory authorities on a potential path forward for palovarotene in patients with FOP. In the meantime, we will collaborate and consult with investigators, ethics committees and regulatory authorities to define next steps for the program, in the best interests of patients.

Ipsen remains deeply committed to supporting those living with FOP. We are working as quickly as possible to establish a path forward for the clinical study of palovarotene as well as to continue to advance our investigational BLU-782 program. We gratefully acknowledge the ongoing support and trust from patients, their families and the healthcare professionals involved in these trials.

If you have further questions, please contact to your physician.

We thank you – study patients and caregivers – for the trust you continue to place in us.

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