Dear FOP Community –

From all of us at Ipsen, we are happy to announce the U.S. Food and Drug Administration’s (FDA) approval of SOHONOS™ (alvalenase) for the reduction in volume of new heterotopic ossification in adults and pediatric patients aged 8 years and older for females and 10 years and older for males with fibrodysplasia ossificans progressiva (FOP). This is an important milestone in the long journey to help improve the management of FOP with a new treatment option. Despite challenges, it was important to us to press on and demonstrate our unwavering dedication to the FOP community.

For us, this milestone fills us with appreciation. We are forever grateful for the partnership of the FOP community – this milestone would not be possible without your involvement in clinical trials. The announcement is also significant to us because as a “first,” it fills us with optimism about the possibilities of additional research in FOP.

We understand for the FOP community in the U.S, the news is deeply personal. It may be the first time someone with FOP could hear the words from their doctor – “there is a treatment we can try.” It may mark the first time a family feels a little more hopeful as they discuss a new treatment option with their doctor. It might also be met with heavy hearts and carry feelings of grief or loss.

On behalf of all at Ipsen, thank you. Thank you for your support.

WHAT IS SOHONOS?
SOHONOS is a prescription medicine used to reduce the amount of new heterotopic ossification in adults and children 8 years of age and older for females and 10 years and older for males with fibrodysplasia ossificans progressiva (FOP). SOHONOS is not recommended for females younger than 8 years of age or males younger than 10 years of age.

IMPORTANT SAFETY INFORMATION
What is the most important information I should know about SOHONOS?
SOHONOS can cause birth defects (deformed babies) if taken during pregnancy. Females who are pregnant or who plan to become pregnant must not take SOHONOS.

- Your healthcare provider may ask you to take a pregnancy test 1 week before starting treatment with SOHONOS, periodically during treatment, and 1 month after you stop treatment.
- You must use effective birth control (contraception) starting at least 1 month before starting treatment with SOHONOS, during treatment, and for 1 month after the last dose. Talk to your healthcare provider about birth control methods that may be right for you.
- If you become pregnant or think you may be pregnant during treatment with SOHONOS, stop taking SOHONOS and call your healthcare provider right away.

Because SOHONOS can cause birth defects, SOHONOS is only for people who can understand and agree to carry out all instructions for pregnancy prevention.

SOHONOS can cause bone growth changes. Children may stop growing while taking SOHONOS. Bone growth changes such as premature closure of the growth plates in growing children have happened with SOHONOS. Your healthcare provider will closely monitor your child’s bone growth and height during treatment with SOHONOS.

Who should not take SOHONOS?
Do not take SOHONOS if you are pregnant, or allergic to medicines known as retinoids or any of the ingredients in SOHONOS.

What should I tell my healthcare provider before taking SOHONOS?
Before taking SOHONOS, tell your healthcare provider about all your medical conditions, including:

- have bone loss (osteoporosis), weak bones or any other bone problems
- have or have had mental health problems
- have or have had kidney problems
- have or have had liver problems
- have had breastfeeding or plan to breastfeed. It is not known if SOHONOS passes into your breastmilk. Call your doctor for medical advice about breastfeeding.

Tell your healthcare provider about all the medicines you take, including:

- dry skin
- dry lips
- hair loss
- itching
- rash
- skin peeling
- skin irritation

These are not all the possible side effects of SOHONOS. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see full Prescribing Information, including Medication Guide with IMPORTANT WARNING.

Sincerely,
David Lowet, CEO Ipsen

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