PRESS RELEASE

Ipsen receives Complete Response Letter for palovarotene, an investigational treatment for fibrodysplasia ossificans progressiva

- The CRL is related to the U.S. FDA's previous request for additional information on palovarotene clinical trial data
- Ipsen anticipates responding to the request in the first quarter of 2023

PARIS, FRANCE, 23 December 2022 – The U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) regarding the New Drug Application for palovarotene, an investigational treatment for the reduction of new abnormal bone formation (heterotopic ossification) in people living with fibrodysplasia ossificans progressiva (FOP). The CRL is related to the regulatory agency's previous request for additional information on palovarotene clinical trial data communicated to Ipsen in October 2022, which is not a request for additional efficacy or safety data beyond existing studies. Ipsen anticipates responding to the request in the first quarter of 2023 with an expected six-month FDA review cycle. The FDA has not announced a rescheduled date for the Endocrinologic and Metabolic Drugs Advisory Committee meeting for investigational palovarotene.

"Although this extends the review timeline for palovarotene, we continue to work with the FDA to provide the requested information and believe that investigational palovarotene has the potential to be an innovative treatment to reduce new abnormal bone formation to slow the progression of FOP," said Howard Mayer, Executive Vice President and Head of Research and Development for Ipsen. "Currently, people living with FOP in the U.S. have no approved treatment option to slow the progression of the disease and this remains our reason for being steadfast in our pursuit of bringing this potential treatment option for FOP."

FOP is an ultra-rare disease that causes permanent and continuous bone formation in soft and connective tissues like muscles, tendons and ligaments, also known as heterotopic ossification or HO.[1] As bone continuously accumulates over time in joints and other areas of the body with flare-up episodes causing rapid bone formation, FOP severely restricts mobility and function.[2] FOP impacts the lives of fewer than an estimated 400 people in the U.S. and 900 people globally.[3] Due to abnormal bone formation, in childhood and early adulthood people living with FOP may lose the permanent ability to move their neck, back, shoulders, chest, legs and arm joints.[4] Without disease-modifying treatment, palliative care is the only treatment option and the median life expectancy is 56 years with untimely death caused by bone formation around the ribcage leading to breathing problems and cardiorespiratory failure.[2]

About palovarotene

Palovarotene is authorized for use in appropriate patients in Canada and United Arab Emirates where it is marketed as Sohonos™ (palovarotene capsules).[4] Investigational palovarotene is under review with a number of regulatory authorities.

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About Ipsen

Ipsen is a global, mid-sized biopharmaceutical company focused on transformative medicines in Oncology, Rare Disease and Neuroscience. With Specialty Care sales of €2.6bn in FY 2021, Ipsen sells medicines in over 100 countries. Alongside its external-innovation strategy, the Company's research and

development efforts are focused on its innovative and differentiated technological platforms located in the heart of leading biotechnological and life-science hubs: Paris-Saclay, France; Oxford, U.K.; Cambridge, U.S.; Shanghai, China. Ipsen has around 5,000 colleagues worldwide and 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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The forward-looking statements, objectives and targets contained herein are based on Ipsen's management strategy, current views and assumptions. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated herein. All of the above risks could affect Ipsen's future ability to achieve its financial targets, which were set assuming reasonable macroeconomic conditions based on the information available today. Use of the words 'believes', 'anticipates' and 'expects' and similar expressions are intended to identify forward-looking statements, including Ipsen's expectations regarding future events, including regulatory filings and determinations. Moreover, the targets described in this document were prepared without taking into account external growth assumptions and potential future acquisitions, which may alter these parameters. These objectives are based on data and assumptions regarded as reasonable by Ipsen. These targets depend on conditions or facts likely to happen in the future, and not exclusively on historical data. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties, notably the fact that a promising medicine in early development phase or clinical trial may end up never being launched on the market or reaching its commercial targets, notably for regulatory or competition reasons. Ipsen must face or might face competition from generic medicine that might translate into a loss of market share. Furthermore, the research and development process involves several stages each of which involves the substantial risk that Ipsen may fail to achieve its objectives and be forced to abandon its efforts with regards to a medicine in which it has invested significant sums. Therefore, Ipsen cannot be certain that favorable results obtained during preclinical trials will be confirmed subsequently during clinical trials, or that the results of clinical trials will be sufficient to demonstrate the safe and effective nature of the medicine concerned. There can be no guarantees a medicine will receive the necessary regulatory approvals or that the medicine will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Other risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and healthcare legislation; global trends toward healthcare cost containment; technological advances, new medicine and patents attained by competitors; challenges inherent in new-medicine development, including obtaining regulatory approval; Ipsen's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Ipsen's patents and other protections for innovative medicines; and the exposure to

litigation, including patent litigation, and/or regulatory actions. Ipsen also depends on third parties to develop and market some of its medicines which could potentially generate substantial royalties; these partners could behave in such ways which could cause damage to Ipsen's activities and financial results. Ipsen cannot be certain that its partners will fulfil their obligations. It might be unable to obtain any benefit from those agreements. A default by any of Ipsen's partners could generate lower revenues than expected. Such situations could have a negative impact on Ipsen's business, financial position or performance. Ipsen expressly disclaims any obligation or undertaking to update or revise any forward-looking statements, targets or estimates contained in this press release to reflect any change in events, conditions, assumptions or circumstances on which any such statements are based, unless so required by applicable law. Ipsen's business is subject to the risk factors outlined in its registration documents filed with the French Autorité des Marchés Financiers. The risks and uncertainties set out are not exhaustive and the reader is advised to refer to Ipsen's 2021 Universal Registration Document, available on ipsen.com

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[1] Kaplan FS, et al. The medical management of fibrodysplasia ossificans progressiva: current treatment considerations. Proc Intl Clin Council FOP 1:1-111, 2019.
[2] Pignolo, RJ et al. Bone. 2020; 134:115274.
[3] Liljesthröm M, Pignolo RJ, Kaplan FS. Epidemiology of the Global Fibrodysplasia Ossificans Progressiva (FOP) Community. J Rare Dis Res Treat. (2020) 5(2): 31-36
[4] Ipsen Press Release 24 January 2022. Available at https://www.ipsen.com/press-releases/health-canada-approves-ipsens-sohonos-palovarotene-capsules-as-the-first-approved-treatment-for-fibrodysplasia-ossificans-progressiva/