PRESS RELEASE

Ipsen receives new FDA PDUFA date for investigational palovarotene for the treatment of people with FOP

- PDUFA date has been set for 16 August 2023 following the New Drug Application resubmission containing additional information on palovarotene clinical trial data, requested in a complete response letter to Ipsen in December 2022

PARIS, FRANCE, 16 March 2023 – Ipsen (Euronext: IPN; ADR: IPSEY) today announced that the U.S. Food and Drug Administration (FDA) Prescription Drug User Fee Act (PDUFA) goal date, for the resubmitted New Drug Application (NDA) for investigational palovarotene as a potential treatment for fibrodysplasia ossificans progressiva (FOP), is 16 August 2023. Additional information on palovarotene clinical trial data, requested in a complete response letter to Ipsen in December 2022, will be reviewed as part of this resubmission process.

If approved, palovarotene, which has received FDA Breakthrough Therapy and Orphan Drug designations, would be the first treatment for an estimated 400 people in the U.S. living with FOP, an ultra-rare, progressive, life-limiting bone disease.[1,2]

Data submitted to the FDA include additional analyses from across the palovarotene clinical trial program, including the pivotal MOVE study,[3] the first Phase III study carried out in people with FOP.

Furthermore, Ipsen has requested a re-examination of the European Medicines Agency's January 2023 Committee for Medicinal Products for Human Use (CHMP) opinion on palovarotene.

Palovarotene is authorized for use in appropriate patients in Canada where it is marketed as Sohonos™ (palovarotene capsules). It also has conditional approval in United Arab Emirates. Investigational palovarotene is under review with several regulatory authorities.

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About FOP

FOP impacts the lives of an estimated 900 people globally.[1,2] The disease continuously progresses with flare-up episodes causing rapid bone growth. Most people living with FOP inevitably lose the ability to eat and drink on their own, cannot provide self-care or use the restroom themselves, and are unable to maintain employment.[4] By the age of 30 years old, the majority of people with FOP require a wheelchair and full-time caregiver assistance.[1] Without disease-modifying treatments, current management is limited to palliative care and ultimately FOP shortens the median life expectancy to 56 years, as untimely death is caused by bone formation around the ribcage leading to breathing problems and cardiorespiratory failure.[4]
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About the MOVE trial

MOVE (NCT03312634) is a Phase III, multicenter, single-arm, open-label trial to assess the efficacy and safety of palovarotene. 107 study participants with FOP received oral palovarotene as a chronic (5mg once daily) and episodic (20mg once daily for 4 weeks, followed by 10mg for ≥8 weeks for flare-ups and

trauma) regimen. The primary endpoint was annualized change in new HO (Heterotopic Ossification) volume measured by low-dose whole-body computed tomography. Efficacy data from participants enrolled in MOVE were compared with data from FOP Natural History Study (NHS) participants, untreated beyond standard of care. Individuals ≤65 years of age with clinically diagnosed FOP and a verified ACVR1R206H pathogenic variant were eligible for inclusion in the NHS.

Results from the post-hoc interim three analysis demonstrated a clinically meaningful 60 percent reduction in new abnormal bone formation HO volume in participants treated with palovarotene, compared to patients on standard of care. Palovarotene also demonstrated a well-characterized safety profile consistent with other therapies in the systemic retinoids class.[3]

These data were published in the Journal of Bone and Mineral Research in December 2022. [https://doi.org/10.1002/jbmr.4762]

About Ipsen
Ipsen is a global, mid-sized biopharmaceutical company focused on transformative medicines in Oncology, Rare Disease and Neuroscience. With total sales of €3.0bn in FY 2022, 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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Ipsen's forward-looking statements
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 latest Universal Registration Document, available on ipsen.com.

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1. 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
2. Pignolo, RJ et al. Bone. 2020; 134:115274.
3. Pignolo, RJ et al. J Bone Miner Res. https://doi.org/10.1002/jbmr.4762
4. Al Mukaddam M, et al. *Val Health* 2022;25:S273 (POSA427)