PRESS RELEASE

Ipsen announces U.S. FDA Priority Review for palovarotene New Drug Application in patients with fibrodysplasia ossificans progressiva following resubmission

PARIS, France, 29 June 2022 – Ipsen (Euronext: IPN; ADR: IPSEY) today announced that the U.S. Food and Drug Administration (FDA) has accepted for Priority Review its resubmitted New Drug Application (NDA) for investigational palovarotene for the treatment of patients with fibrodysplasia ossificans progressiva (FOP), an ultra-rare genetic disorder. Ipsen is seeking approval of palovarotene, an oral, selective retinoic-acid receptor gamma (RARγ) agonist for the prevention of heterotopic ossification (HO; new bone formation outside of the normal skeletal system). The FDA has assigned 29 December 2022 as the Prescription Drug User Fee Act goal date, which is on track with anticipated regulatory submission timelines.

"This FDA submission acceptance marks a significant milestone for those living with FOP in the U.S. where no approved treatment options exist today for this progressive and debilitating ultra-rare genetic disorder," said Dr. Howard Mayer, Executive Vice President and Head of Research and Development, Ipsen. "Ipsen is committed to developing life-changing treatments for patients living with rare diseases despite the challenges that exist when there are few, or no precedents to build on when developing a new, innovative medicine for a complex condition. We remain committed to the FOP community, and we hope the Priority Review is one step closer towards getting a much needed treatment to people living with FOP as soon as possible."

The FDA's Priority Review designation is assigned to investigational therapies that, if approved, represent a significant improvement in the safety or effectiveness of the treatment compared to the current standard of care.

In January 2022, Health Canada was the first regulatory authority to approve Sohonos™ (palovarotene capsules) to reduce the formation of HO in adults and children aged 8 years and above for females and 10 years and above for males with FOP. Sohonos is approved in Canada for the treatment of patients with FOP for both chronic use and for flare-ups in these patient populations. Palovarotene is not currently approved outside of Canada. A Marketing Authorization Application for palovarotene has also been filed in the E.U. in 2021, with responses to questions raised by the European Medicines Agency submitted in June 2022, in line with the ongoing regulatory process. Ipsen anticipates additional applications to other regulatory agencies in due course.

FOP has an estimated prevalence of 1.36 per million individuals; however, the number of confirmed cases varies by country.[1,2] It is characterized by new bone formation outside of the normal skeletal system, like in soft connective tissues, a process known as HO,[3] which can be preceded by painful soft-tissue swelling or 'flare-ups'.[2] Flare-up episodes are common and are a substantial contributor to the formation of new HO, however HO can form in the absence of a flare-up. HO, once formed, is irreversible and leads to loss of mobility and shortened life expectancy.[3]

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About palovarotene
Palovarotene is an oral investigational, selective retinoic-acid receptor gamma (RARγ) agonist being developed as a potential treatment for people living with the debilitating ultra-rare genetic disorder fibrodysplasia ossificans progressiva (FOP). Palovarotene, which received rare pediatric disease and Breakthrough Therapy Designations from the U.S. Food and Drug Administration (FDA) for the potential treatment of FOP, was acquired by Ipsen through the acquisition of Clementia Pharmaceuticals in April 2019. The palovarotene New Drug Application (NDA) was initially accepted by the FDA for Priority Review on May 28, 2021, and Ipsen announced withdrawal of the NDA on August 13, 2021. The resubmission of the palovarotene NDA has been accepted by the FDA for Priority Review in the U.S.

About fibrodysplasia ossificans progressiva (FOP)
Fibrodysplasia ossificans progressiva (FOP) is an ultra-rare genetic disorder characterized by bone that forms outside the normal skeleton, in muscles, tendons, or soft tissue.[3] FOP has an estimated prevalence of 1.36 per million individuals globally; however, the number of confirmed cases varies by country.[1,2] The median age at time of FOP diagnosis is five years old.[4]

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, excluding its Consumer HealthCare business, has around 4,500 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 www.ipsen.com.

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 2021 Universal Registration Document, available on **ipsen.com.**

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