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PRESS RELEASE

Health Canada approves Ipsen's Sohonos™ (palovarotene capsules) as the first approved treatment for fibrodysplasia ossificans progressiva

PARIS, France, 24 January 2022 – Ipsen (Euronext: IPN; ADR: IPSEY) today announced the Health Canada approval of Sohonos (palovarotene capsules), an oral selective retinoic-acid receptor gamma (RARγ) agonist indicated to reduce the formation of heterotopic ossification (HO; new bone formation) in adults and children aged 8 years and above for females and 10 years and above for males with fibrodysplasia ossificans progressiva (FOP).[1] Sohonos is approved for the treatment of patients with FOP for both chronic use, and for flare-ups, in these patient populations. This decision marks the first approval for Sohonos worldwide.

Dr. Howard Mayer, Executive Vice President and Head of Research and Development, Ipsen, said "FOP is a progressive and debilitating condition which has such a profound impact on patients, and their families. Until today, there was no approved medicine, and we are proud to bring this important new medicine to the FOP community."

FOP is characterized by new bone formation outside of the normal skeletal system, like in soft connective tissues, a process known as heterotopic ossification,[2] 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 bone, however bone can also form in the absence of a flare-up. Once formed, it is irreversible and leads to loss of mobility and shortened life expectancy.[2] It is an ultra-rare genetic disorder with an estimated prevalence of 1.36 per million individuals; however, the number of confirmed cases varies by country.[3,4].

As part of the ongoing commitment to the FOP and rare disease community, Ipsen plans to file in the US in H1 2022 and is in discussions with other regulatory authorities around the world.

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About the MOVE clinical program
This approval is based on data from the ongoing MOVE trial, the first global multi-center Phase III trial in FOP. MOVE is an open-label, single-arm trial, evaluating the efficacy and safety of a chronic/flare-up dosing regimen of palovarotene in decreasing new annualized HO volume in patients with FOP

About Sohonos
Sohonos is an oral, selective RARγ agonist developed as a treatment for people living with the debilitating ultra-rare genetic disorder, FOP. The treatment was acquired by Ipsen through the acquisition of Clementia Pharmaceuticals in April 2019. It is a member of the retinoid class of drugs that is associated with birth defects in humans. Sohonos must not be used by patients who are, or intend to become, pregnant due to the risk of teratogenicity. To minimize fetal exposure, Sohonos is to be administered only if all conditions for pregnancy prevention are met. Sohonos has been shown to cause premature physeal closure in growing children with FOP; periodic monitoring is recommended.

About Ipsen
Ipsen is a global, mid-sized biopharmaceutical company focused on transformative medicines in Oncology, Rare Disease and Neuroscience; it also has a well-established Consumer Healthcare business. With total sales of over €2.5bn in FY 2020, Ipsen sells more than 20 medicines in over 115 countries, with a direct commercial presence in more than 30 countries. 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 5,700 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.

Forward looking statement

The forward-looking statements, objectives and targets contained herein are based on the Group'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 the Group'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 the Group's expectations regarding future events, including regulatory filings and determinations, and the outcome of this study or other studies. 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 the Group. 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 product 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. The Group must face or might face competition from generic products 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 the Group may fail to achieve its objectives and be forced to abandon its efforts with regards to a product in which it has invested significant sums. Therefore, the Group 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 product concerned. There can be no guarantees a product will receive the necessary regulatory approvals or that the product 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 6 pharmaceutical industry regulation and health care legislation; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the Group'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 the Group's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions. The Group also depends on third parties to develop and market some of its products which could potentially generate substantial royalties; these partners could behave in such ways which could cause damage to the Group's activities and financial results. The Group 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 the Group's partners could generate lower revenues than expected. Such situations could have a negative impact on the Group's business, financial position or performance. The Group 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. The Group'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 the Group's 2020 Universal Registration Document available on its website (www.ipsen.com).

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