

Ipsen Initiates Partial Clinical Hold for Palovarotene IND120181 and IND135403 Studies

PARIS, France, 6 December 2019 -- Ipsen (Euronext: IPN; ADR: IPSEY) today announced, following discussions with the U.S. Food and Drug Administration (FDA), that a partial clinical hold effective immediately, for the pediatric population under the age of 14 was issued for studies conducted under IND120181 and IND135403 evaluating the investigational drug candidate palovarotene for the chronic treatment of fibrodysplasia ossificans progressiva (FOP) and multiple osteochondromas (MO), respectively. The partial clinical hold applies to the pediatric population (patients under the age of 14 years) currently participating in the Phase 2 (PVO-1A-202/204 and PVO-2A-201) and Phase 3 (PVO-1A-301) studies in all clinical sites at global level. The FDA is allowing the studies to continue to treat patients 14 years of age and older.

The partial clinical hold was issued following recent safety reports submitted by the company to the FDA of cases of early growth plate closure in pediatric patients with FOP treated with palovarotene. The FDA has placed the studies on partial clinical hold pending review of additional details regarding these events and plans to issue additional requests for information within the next 30 days. Although no serious adverse events (SAEs) related to early growth plate closure in the MO study have been reported to date, this study has been included in this hold due to the occurrence of these events with chronic dosing in the FOP program. Since the MO study is a primarily pediatric study with the upper age of enrollment at 14 years, all subjects currently participating in the study will have interruption of treatment until further notice and no new patients will be enrolled while the partial clinical hold is in effect.

At Ipsen, the safety of patients is always a top priority, and the company is committed to ensuring the safe and effective use of its medicines. Ipsen is committed to researching and developing therapies for children and adults living with FOP and MO, two rare and devastating bone diseases with no current therapeutic treatment options.

Ipsen is committed to working diligently with the FDA to provide all requested information with the goal of resolving the partial clinical hold. Ipsen continues to prepare the FDA New Drug Application (NDA) filing for palovarotene in acute/flare-up FOP.

About Ipsen

Ipsen is a global specialty-driven biopharmaceutical group focused on innovation and Specialty Care. The Group develops and commercializes innovative medicines in three key therapeutic areas – Oncology, Neuroscience and Rare Diseases. Its commitment to oncology is exemplified through its growing portfolio of key therapies for prostate cancer, neuroendocrine tumors, renal cell carcinoma and pancreatic cancer. Ipsen also has a well-established Consumer Healthcare business. With total sales over €2.2 billion in 2018, Ipsen sells more than 20 drugs in over 115 countries, with a direct commercial presence in more than 30 countries. Ipsen's R&D is focused on its innovative and differentiated technological platforms located in the heart of the leading biotechnological and life sciences hubs (Paris-Saclay, France; Oxford, UK; Cambridge, US). The Group has about 5,800 employees worldwide. Ipsen is listed in Paris (Euronext: IPN) and in the United States through a Sponsored Level I American Depositary Receipt program (ADR: IPSEY). For more information on Ipsen, visit www.ipсен.com.

Ipsen—Cautionary Note Regarding Forward-Looking Statements

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. 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 pre-clinical 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 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 2018 Registration Document available on its website (www.ipsen.com).

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