Ipsen to host an Investor Day to highlight its innovative R&D pipeline and provide financial outlook for 2022

- 5 new chemical entities advancing in pipeline
- 9 significant regulatory submissions planned from 2019 to 2022
- 2022 financial outlook of Group Net Sales around €3.2 billion and Core Operating margin greater than 32.0% of net sales

Paris (France), 14 May 2019 - Ipsen (Euronext: IPN; ADR: IPSEY), a global specialty-driven biopharmaceutical group, today will host an Investor Day in Paris to present a comprehensive corporate update, with a focus on its advancing R&D pipeline.

David Meek, Chief Executive Officer of Ipsen stated: “The business momentum of Ipsen is strong, delivering industry-leading top-line growth and investing to build an innovative and sustainable pipeline. The execution of our R&D strategy over the last two years through accelerating key internal programs and externally sourcing innovation has significantly strengthened the focus and value of our pipeline.

“Ipsen currently has five new chemical entities in clinical development, nine significant regulatory submissions planned from 2019 to 2022 and several mid-to-late-stage program readouts in the coming months. We remain committed to executing on our top-line, bottom-line and pipeline growth strategy to create and deliver long-term value to patients and shareholders.”

In Rare Diseases, palovarotene is a late-stage and largely de-risked drug candidate for the treatment of rare and extremely disabling bone disorders with no current treatment options. Palovarotene has Orphan Drug, Fast Track, Breakthrough Therapy and Rare Pediatric Disease designations and is supported by robust clinical data. The company expects to submit an NDA to the FDA in the second half of 2019 for the first indication of fibrodysplasia ossificans progressiva (FOP).

In Neuroscience, Ipsen is pursuing two new therapeutic indications to maximize the potential of Dysport®. The Company is also leveraging its research and development expertise building upon its neurotoxin franchise to advance its proprietary next-generation neurotoxin program with a fast-acting neurotoxin to enter Phase 2 clinical development in the second half of 2019 and a long-acting neurotoxin in preclinical development.

In Oncology, there are numerous ongoing mid-to-late-stage programs to broaden the scope of Cabometyx® (cabozantinib) and Onivyde® (irinotecan liposomal). The Phase 3 CheckMate 9ER trial in combination with nivolumab has the potential to strengthen Cabometyx®’s presence in the first-line renal cell cancer market, with top-line results expected in the first half of 2020. In addition, the Phase 3 trial in combination with atezolizumab for first-line hepatocellular carcinoma has the potential to expand the use of Cabometyx® earlier in the treatment paradigm and to serve as the registrational trial to enter China.

Regarding Onivyde®, the interim analysis of the Phase 2 combination trial for the treatment of first-line metastatic pancreatic cancer indicates encouraging results on the disease control rate and has been accepted as an oral presentation by the ESMO World Congress on Gastrointestinal Cancer in July 2019. There is also an ongoing Phase 2 trial for second-line small cell lung cancer with top-line results expected in the second half of 2019.

In earlier-stage Oncology development, Ipsen is advancing its innovative Systemic Radiation Therapy program with satoreotide (IPN 1070 and IPN 1072) which is expected to move into a Phase 2/3 trial in neuroendocrine

1 Assuming current level of exchange rates
tumors by the first quarter of 2020 and IPN 1087 which is currently in Phase 1 development for pancreatic cancer. Both are platform technologies with the possibility to expand to additional solid tumors and to provide precision targeted treatment to patients.

Ipsen will also execute on its external innovation and business development model in its key therapeutic areas, building on its strong balance sheet and cash flow generation to acquire assets and invest in R&D pipeline for long term shareholders’ value.

Along with an R&D pipeline update, Ipsen will also provide updates on its corporate strategy, commercial highlights of its key Specialty Care products, and new objectives on its capital allocation strategy and mid-term financial outlook.

2022 Financial outlook
Ipsen provides its 2022 financial outlook to reflect the strong momentum of its Specialty Care business and the impact from the acquisition of Clementia closed in April 2019:

- Group Net Sales around €3.2 billion\(^2\)
- Core Operating margin greater than 32.0% of net sales

This outlook includes only the existing commercial portfolio of products under current approved indications and assumes the approval and launch of palovarotene in FOP indications\(^3\) only. It assumes the earliest possible entry of somatostatin analog (SSA) generics based on market intelligence. It does not include the potential short-term, low single-digit Core Operating margin dilution of business development transactions to further accelerate building an innovative and sustainable pipeline.

Webcast and Conference call
Ipsen will host an audio and video webcast and conference call of the Investor Day on Tuesday 14 May 2019 at 1:00 p.m. (CET, GMT+1) available at www.ipsen.com. Participants should dial in to the call approximately 5 to 10 minutes prior to its start. No reservation is required to participate in the conference call.

Standard International: +44 (0) 2071-928-000
France and continental Europe: + 33 (0) 1 76 70 07 94
UK: 08-445-718-892
U.S.: 1-6315-107-495

Conference ID: 8463129

A recording will be available for 7 days on Ipsen’s website.

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 5,700

\(^2\) Assuming current level of exchange rates

\(^3\) Including both flare-up and chronic indications for FOP
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.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. 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 fulfill 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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