PRESS RELEASE

# Ipsen reports solid sales growth in first quarter 2020 with limited COVID-19 impact

- **Continued momentum with Q1 2020 Group sales growth of 9.6% as reported, or 8.7%[1] at constant exchange rates**
- **Limited Q1 2020 financial impact from COVID-19 given resilient Specialty Care product portfolio comprised mostly of highly-differentiated treatments for critical conditions. Levels of inventory are adequate and no supply chain issues are anticipated. Limited disruption to ongoing clinical trials**
- **2020 Guidance remains suspended as announced in March given the uncertainty around the duration and scale of the COVID-19 pandemic**
- **Significant progress for palovarotene with clearance to re-initiate dosing in fibrodysplasia ossificans progressiva (FOP) patients 14 years of age and older, and complete response submitted to the FDA's questions related to the partial clinical hold on patients under 14 years of age in palovarotene trials**
- **Focus on near-term priorities: executing on COVID-19 business continuity plan, identifying a new CEO and determining the regulatory pathway for palovarotene for FOP**

**Paris (France), 22 April 2020 -** Ipsen (Euronext: IPN; ADR: IPSEY), a global specialty-driven biopharmaceutical group, today announced its sales for the first quarter of 2020.

**Aymeric Le Chatelier, Chief Executive Officer and Chief Financial Officer** of Ipsen stated: *"Thanks to the resilient Specialty Care product portfolio, the Group delivered solid sales growth in the first quarter with limited impact from COVID-19. Our priorities in these unprecedented times are to ensure the safety of our employees as well as driving business continuity so patients can maintain access to important medicines. Our 2020 guidance remains suspended until we have more visibility.*

*"During the first quarter, we received authorization to re-initiate dosing of palovarotene in patients with FOP and are now focused on working with the FDA and other agencies on defining a regulatory path forward with the objective of bringing palovarotene to FOP patients as quickly as possible.*

*"Thanks to the continued commitment and dedication of our people around the world, we are mobilized to face the COVID-19 pandemic. Together, we will continue to advance and strengthen our pipeline and drive growth and sustainability to fulfill our mission of improving patients' lives."*

[1] At constant exchange rates. Year-on-year growth excluding foreign exchange impact established by recalculating net sales for the relevant period at the rate used for the previous period.

## First quarter sales

First quarter 2020 unaudited IFRS consolidated sales

| *(in million euros)* | **Q1 2020** | **Q1 2019** | *% Change* | *% Change at constant currency[1]* |
|---|---|---|---|---|
| Specialty Care | 602.6 | 530.9 | *+13.5%* | *+12.5%* |
| Consumer Healthcare | 52.0 | 66.3 | *-21.5%* | *-21.9%* |
| **Group Sales** | **654.6** | **597.2** | ***+9.6%*** | ***+8.7%*** |

Continuing its growth trajectory, Ipsen achieved solid Group sales growth of 9.6% as reported, or 8.7%[1] at constant exchange rates in the first quarter of 2020.

- Specialty Care sales growth of 12.5%[1], reflecting continued strong double-digit growth of Somatuline® (*lanreotide*) and the continued growth of Cabometyx® (*cabozantinib*) and Decapeptyl® (*triptorelin*).
- Consumer Healthcare sales down by 21.9%, mainly related to China with the negative impact of the implementation of hospital central procurement and COVID-19.

## COVID-19 update

In the first quarter of 2020, the business remained strong with COVID-19 having a limited impact on sales due to increased stocking in the Oncology portfolio in some European countries toward the end of first quarter. This offsets a lower demand in China in February and March which had a significant impact on the Consumer Healthcare portfolio.

Ipsen continues to operate all of its manufacturing sites and is closely monitoring the situation. There is an adequate level of inventory with no supply chain issues anticipated to continue providing medicines to patients. There is also limited impact to date on clinical trials, with minimal disruption to investigational drug supply for ongoing patients, despite a general slowdown in the recruitment of new patients as well as new site activations in ongoing trials across Europe and the U.S.

Ipsen remains focused on ensuring that patients continue to have access to their treatments and on addressing the impact of this pandemic in their communities. Most Ipsen employees around the world, excluding mainly those at the manufacturing and distribution sites, are working from home today, and the commercial organization continues to support healthcare providers virtually.

In the second quarter of 2020, the situation in China should improve as business begins to resume. However, despite Ipsen's sustainable and resilient Oncology portfolio comprised mostly of highly-differentiated long-acting treatments for critical conditions, there is expected to be some impact from delayed diagnoses and lower new patient gains. It is also anticipated that there will be more of a negative impact on Dysport sales and revenues in both the therapeutics and aesthetics markets with delayed injections.

## 2020 Guidance

As announced on March 25th, the 2020 guidance remains suspended due to the lack of visibility on all the consequences of the global COVID-19 pandemic despite a resilient Oncology portfolio. It is not possible at this stage to quantify the impact on the Group's financial statements. Further updates will be provided as the situation evolves.

[1] At constant exchange rates. Year-on-year growth excluding foreign exchange impact established by recalculating net sales for the relevant period at the rate used for the previous period.

**Palovarotene update**

In the last few months, Ipsen made significant progress on advancing palovarotene, a top priority for the company. On 26 March 2020, clearance was received from the U.S. Food and Drug Administration (FDA) and other regulatory authorities to re-initiate palovarotene dosing in patients 14 years of age and older in the fibrodysplasia ossificans progressiva (FOP) clinical program. It was also decided to terminate the Phase 2 MO-Ped trial in patients with multiple osteochondromas (MO) in order to analyze the accumulated data and to better inform on the efficacy, safety and future of palovarotene in MO. A Complete Response was recently submitted to address the FDA's questions related to the partial clinical hold on patients under 14 years of age in palovarotene trials.

**Positive topline results from pivotal Phase 3 CheckMate -9ER trial**

CheckMate -9ER, a pivotal Phase 3 trial evaluating Cabometyx in combination with Opdivo (nivolumab) compared to sunitinib in previously untreated advanced or metastatic renal cell carcinoma (RCC), met its primary endpoint of progression-free survival (PFS) at final analysis, as well as the secondary endpoints of overall survival (OS) at a pre-specified interim analysis, and objective response rate (ORR).

The safety profiles of Cabometyx and Opdivo observed in the trial reflect the known safety profiles of the immunotherapy and tyrosine kinase inhibitor components in first-line RCC.

Detailed results of CheckMate -9ER will be submitted for presentation at an upcoming medical conference.

**2020 Near-term priorities**

Ipsen remains focused on the following near-term priorities:

- COVID-19: Ipsen will effectively manage the developing situation of COVID-19 by ensuring the safety of all employees and business continuity for patients as well as preparing for business recovery including protecting profitability and cash flow generation.
- CEO search: The board of directors is progressing with its search for a new CEO with no delay expected due to COVID-19.
- Palovarotene program: Ipsen intends to engage with the FDA and other regulatory authorities on the appropriate patient population eligible for treatment and a potential regulatory path forward for palovarotene in FOP.

**2020 Annual Shareholders' Meeting and proposed distribution of €1.00 per share confirmed**

The Annual Shareholders' Meeting will be held on 29 May 2020 behind closed doors, without the physical attendance of shareholders. It will be broadcast via a link provided on Ipsen's website. Ipsen will request its shareholders to cast their votes remotely and submit their questions in advance.

Furthermore, the company confirms the proposed distribution of €1.00 per share for the 2019 financial year to be paid on 5 June 2020. The ex-dividend date is set for 3 June 2020.

**Conference call details**

Ipsen will hold a conference call on Wednesday, 22 April 2020 at 2:30 p.m. (Paris time, GMT+1). Participants should dial in to the call approximately 15 minutes prior to its start. Participants can register for the call on the link below:
http://emea.directeventreg.com/registration/7159233

A recording will be available for seven 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 €2.5 billion in 2019, 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.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 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 2019 Universal Registration Document available on its website (www.ipsen.com).

## For further information:


**Media**
**Christian Marcoux, M.Sc.**
Senior Vice President, Global Communications
+33 (0)1 58 33 67 94
Christian.marcoux@ipsen.com

**Fanny Allaire**
Director, Ipsen France Hub, Global Communications
+33 (0) 1 58 33 58 96
Fanny.allaire@ipsen.com

**Financial Community**
**Eugenia Litz**
Vice President, Investor Relations
+44 (0) 1753 627721
Eugenia.litz@ipsen.com

**Myriam Koutchinsky**
Investor Relations Manager
+33 (0)1 58 33 51 04
Myriam.koutchinsky@ipsen.com

## Comparison of Consolidated Sales for the First Quarter 2020 and 2019:

***Sales by therapeutic area and by product***

| | 1st Quarter | | | |
|---|---|---|---|---|
| (in million euros) | **2020** | **2019** | % Variation | % Variation at constant currency[1] |
| Oncology | **492.6** | **420.7** | **17.1%** | **15.7%** |
| Somatuline® | 285.5 | 235.5 | 21.2% | 19.5% |
| Decapeptyl® | 96.6 | 88.7 | 8.9% | 8.6% |
| Cabometyx® | 72.4 | 53.9 | 34.2% | 34.3% |
| Onivyde® | 31.2 | 34.6 | -10.0% | -13.3% |
| Other Oncology | 7.0 | 8.0 | -12.6% | -12.7% |
| Neuroscience | **93.5** | **94.3** | **-0.9%** | **-0.6%** |
| Dysport® | 92.9 | 93.8 | -0.9% | -0.6% |
| Rare Diseases | **16.5** | **15.8** | **4.6%** | **3.9%** |
| NutropinAq® | 11.1 | 10.5 | 6.0% | 6.1% |
| Increlex® | 5.4 | 5.3 | 1.9% | -0.3% |
| **Specialty Care** | **602.6** | **530.9** | **13.5%** | **12.5%** |
| Smecta® | 17.9 | 29.9 | -40.2% | -40.5% |
| Tanakan® | 10.2 | 9.4 | 8.7% | 7.9% |
| Forlax® | 9.8 | 8.5 | 15.9% | 15.7% |
| Fortrans/Eziclen® | 6.8 | 7.8 | -12.7% | -13.8% |
| Other Consumer Healthcare | 7.3 | 10.7 | -31.9% | -32.0% |
| **Consumer Healthcare** | **52.0** | **66.3** | **-21.5%** | **-21.9%** |
| **Group Sales** | **654.6** | **597.2** | **9.6%** | **8.7%** |

**First quarter 2020 sales highlights**

Group sales reached €654.6 million, up 8.7%[1], driven by Specialty Care sales growth of 12.5%[1], while Consumer Healthcare sales decreased by 21.9%[1].

**Specialty Care** sales amounted to €602.6 million, up 12.5%[1]. Oncology sales grew by 15.7%[1] while Neuroscience and Rare Diseases sales decreased by 0.6%[1] and 3.9%[1], respectively. Over the period, the relative weight of Specialty Care continued to increase to reach 92.1% of total Group sales, compared to 88.9% in 2019.

In **Oncology,** sales reached €492.6 million, up 15.7%[1] year-on-year, driven by continued strong performance across most major products and geographies and a higher level of orders at the end of March in Europe due to COVID-19. Over the period, Oncology sales represented 75.2% of total Group sales, compared to 70.5% in 2019.

**Somatuline** – Sales reached €285.5 million, up 19.5%[1] year-on-year, driven by 20.3%[1] growth in North America primarily from volume growth, along with continued double-digit growth in Europe fueled by market share gains and COVID-19 positive stocking to offset the limited impact from the octreotide generic.

[1] At constant exchange rates. Year-on-year growth excluding foreign exchange impact established by recalculating net sales for the relevant period at the rate used for the previous period.

**Decapeptyl** – Sales reached €96.6 million, up 8.6%[1] year-on-year, driven mainly by solid volume growth in Major Western Europe countries and Algeria. The negative impact of COVID-19 in China was partly offset by high orders at the end of Q1 2020 in Europe.
**Cabometyx** – Sales reached €72.4 million, up 34.3%[1] year-on-year, driven by good performance across geographies and an inventory increase in Major Western European countries due to COVID-19 stocking.
**Onivyde** – Sales reached €31.2 million, down 13.3%[1], impacted by a significant decline in sales to Ipsen's ex-U.S. partner despite growing demand in the U.S.

In **Neuroscience**, sales of **Dysport** reached €92.9 million, down 0.6%[1], impacted by lower therapeutics sales in Europe, importation delays in the Middle East and Africa as well as delayed injections related to COVID-19 at the end of March, despite Galderma's solid performance in the aesthetics markets in Europe and North America. Over the period, Neuroscience sales represented 14.3% of total Group sales, compared to 15.8% in 2019.

In **Rare Diseases**, sales of **NutropinAq** reached €11.1 million, up 6.1%[1] year-on-year, driven by volume growth in Germany. Sales of **Increlex** reached €5.4 million, down 0.3%[1] year-on-year mainly due to lower demand in the U.S. Over the period, Rare Diseases sales represented 2.5% of total Group sales, compared to 2.6% in 2019.

**Consumer Healthcare** sales reached €52.0 million, down 21.9%[1], driven by a decline in Smecta sales of 40.5%[1] year-on-year mainly due the negative impact of the implementation of hospital central procurement and COVID-19. Fortrans/Eziclen sales were down 13.8%[1] year-on-year, mainly due to China and Vietnam. Tanakan year-on-year sales were up 7.9%[1], driven by positive market dynamic in Russia. Over the period, Consumer Healthcare sales represented 7.9% of total Group sales, compared to 11.1% in 2019.

[1] At constant exchange rates. Year-on-year growth excluding foreign exchange impact established by recalculating net sales for the relevant period at the rate used for the previous period.

### *Sales by geographical area*

| (in million euros) | 1st Quarter 2020 | 1st Quarter 2019 | % Variation | % Variation at constant currency[1] |
|---|---|---|---|---|
| France | 78.7 | 82.0 | -4.0% | -4.4% |
| Germany | 50.3 | 45.4 | 10.8% | 10.8% |
| Italy | 35.2 | 29.8 | 18.4% | 18.4% |
| United Kingdom | 30.0 | 25.2 | 19.3% | 16.7% |
| Spain | 29.9 | 23.8 | 25.5% | 25.5% |
| **Major Western European Countries** | **224.1** | **206.1** | **8.7%** | **8.2%** |
| Eastern Europe | 57.3 | 47.8 | 20.0% | 18.5% |
| Other Europe | 74.8 | 65.8 | 13.7% | 14.4% |
| **Other European Countries** | **132.1** | **113.5** | **16.3%** | **16.1%** |
| **North America** | **215.5** | **179.2** | **20.2%** | **16.8%** |
| Asia | 31.6 | 50.4 | -37.3% | -37.7% |
| Other countries in the Rest of the world | 51.4 | 47.9 | 7.2% | 10.7% |
| **Rest of the World** | **83.0** | **98.3** | **-15.6%** | **-14.1%** |
| **Group Sales** | **654.6** | **597.2** | **9.6%** | **8.7%** |

Sales in **Major Western European countries** reached €224.1 million, up 8.2%[1] year-on-year. Over the period, sales in Major Western European countries represented 34.2% of total Group sales, compared to 34.5% in 2019.

**France** – Sales reached €78.7 million, down 4.4%[1] year-on-year, impacted by lower Onivyde sales to Ipsen's ex-U.S. partner and lower Consumer Healthcare performance despite continued growth in Oncology with solid performance and higher orders at the end of Q1 2020 related to COVID-19 stocking.

**Germany** – Sales reached €50.3 million, up 10.8%[1] year-on-year, driven by continued solid volume growth of Somatuline despite the octreotide generic, along with inventory increase across the Oncology and Rare Disease portfolio related to COVID-19 stocking.

**Italy** – Sales reached €35.2 million, up 18.4%[1] year-on-year, driven by good performance of Cabometyx from the front-line RCC indication launch and COVID-19 stocking at the end of Q1 2020 in Oncology.

**United Kingdom** – Sales reached €30.0 million, up 16.7%[1] year-on-year, driven by Cabometyx and the solid performance of Decapeptyl including COVID-19 stocking.

**Spain** – Sales reached €29.9 million, up 25.5%[1] year-on-year, driven by the growth of Decapeptyl, Cabometyx and Somatuline, reflecting solid performance in Q1 2020 and COVID-19 stocking in March.

Sales in **Other European countries** reached €132.1 million, up 16.1%[1] year-on-year, driven by the launch of Cabometyx in several countries and the continued strong growth of Somatuline, along with good performance of Tanakan in Russia. Over the period, sales in the region represented 20.2% of total Group sales, compared to 19.0% in 2019.

Sales in **North America** reached €215.5 million, up 16.8%[1] year-on-year, driven by continued strong demand of Somatuline and steady growth of Onivyde and Dysport. Over the period, sales in North America represented 32.9% of total Group sales, compared to 30.0% in 2019.

[1] At constant exchange rates. Year-on-year growth excluding foreign exchange impact established by recalculating net sales for the relevant period at the rate used for the previous period.

Sales in the **Rest of the World** reached €83.0 million, down 14.1%[1] year-on-year, driven by the negative impact of COVID-19 in China mainly affecting Decapeptyl and Smecta, partly offset by the good performance of Somatuline and Cabometyx mainly in Brazil and Australia. Over the period, sales in the Rest of the World represented 12.7% of total Group sales, compared to 16.5% in 2019.

[1] At constant exchange rates. Year-on-year growth excluding foreign exchange impact established by recalculating net sales for the relevant period at the rate used for the previous period.