

## Ipsen delivers sales growth in the first nine months of 2020 despite the impact of COVID-19 and confirms its 2020 full year guidance

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

- **Q3 2020 Group sales growth** of +2.2%<sup>1</sup> at constant exchange rates and decrease of -1.8% as reported, driven by Specialty Care sales growth of 5.1%<sup>1</sup> despite the continuing negative COVID-19 impact. Positive Q3 performance results in YTD sales growth of +2.8%<sup>1</sup> at constant exchange rates and +1.5% as reported.
- **Confirmation of 2020 full year guidance**, with Group sales growth greater than +2.0% at constant currency and Core Operating margin greater than 30.0% of net sales.
- **Key Q3 pipeline progress:**
  - **Cabometyx® (cabozantinib):** Presentation at the ESMO 2020 Virtual Congress of the Phase III CheckMate -9ER trial in patients with previously untreated advanced renal cell carcinoma, in which Cabometyx in combination with nivolumab met all key efficacy endpoints of overall survival, progression-free survival and objective response rate. The results were consistent across the pre-specified International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) risk and PD-L1 expression subgroups.
  - **Palovarotene:** Presentation at the American Society for Bone and Mineral Research (ASBMR) 2020 Annual Meeting of post hoc analyses from the Phase III MOVE trial investigating palovarotene as a chronic and episodic treatment for patients with fibrodysplasia ossificans progressiva (FOP).
- **Appointment of Philippe Lopes-Fernandes as Executive Vice President, Chief Business Officer**, effective 1 October 2020, with responsibility for business development and alliance management.

**David Loew, Chief Executive Officer of Ipsen** stated: *“The Group delivered a resilient performance in the third quarter, despite the continued impact of the pandemic, and I am pleased to confirm our 2020 full year financial objectives. Our pipeline achieved notable progress with incremental positive data on Cabometyx and palovarotene, supporting our intention to bring these important therapies to patients. I look forward to sharing my long-term vision for Ipsen and the outcomes of a comprehensive strategic review at our Capital Markets Day on December 1<sup>st</sup>.”*

### Key figures

Unaudited IFRS consolidated sales

(in million euros)	Third Quarter				Nine Months			
	2020	2019	% Variation	% Variation at constant currency	2020	2019	% Variation	% Variation at constant currency
Specialty Care	580.5	574.2	1.1%	5.1%	1,747.6	1,674.1	4.4%	5.7%
Consumer Healthcare	52.8	70.6	-15.5%	-21.9%	154.0	200.2	-23.1%	-21.4%
<b>Group sales</b>	<b>633.3</b>	<b>644.7</b>	<b>-1.8%</b>	<b>2.2%</b>	<b>1,901.6</b>	<b>1,874.3</b>	<b>1.5%</b>	<b>2.8%</b>

<sup>1</sup>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.

## **COVID-19 impact**

In the third quarter of 2020, the business recovered gradually from the impact of COVID-19. While the Specialty Care portfolio comprised of differentiated products for critical conditions remained relatively resilient, Somatuline, Decapeptyl and Onivyde sales were negatively impacted by lower patient diagnoses and missed treatments due to the ongoing impact of the pandemic and the challenging hospital environment. In neuroscience, the aesthetics market showed a stronger recovery, while the therapeutics market rebounded more slowly with the gradual re-opening of injection centers. Consumer Healthcare sales, notably Smecta, continued to be negatively impacted across geographies.

The Group continued to realize cost savings in the third quarter, resulting from digital sales detailing, lower travel throughout the Group and the conversion to virtual conference and medical meetings.

## **2020 Guidance confirmed**

The Group confirms the following financial targets for the current year:

- **Group sales growth greater than +2.0%** at constant currency, with an expected negative impact of 1.5% from currencies based on the level of exchange rates at the end of September.
- **Core Operating margin greater than 30.0% of net sales**

## **Recent pipeline highlights**

- Positive results of the Phase III CheckMate -9ER trial presented at the ESMO Congress, in which Cabometyx<sup>®</sup> in combination with Bristol Myers Squibb's Opdivo<sup>®</sup> (*nivolumab*) demonstrated significant improvements across all efficacy endpoints, including superior overall survival (OS), a doubling of median progression-free survival (PFS) and superior objective response rate (ORR) versus sunitinib, with a favorable safety profile in previously untreated advanced renal cell carcinoma (RCC). Key efficacy results were consistent across the pre-specified International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) risk and PD-L1 expression subgroups. The regulatory filing has been submitted and validated by the EMA, thus beginning the centralized review process.
- At the American Society for Bone and Mineral Research (ASBMR) 2020 Annual Meeting, Ipsen presented post hoc analyses from the Phase III MOVE trial investigating palovarotene as a chronic and episodic treatment for fibrodysplasia ossificans progressiva (FOP) in both pediatric and adult patients, with palovarotene demonstrating a 62% reduction in mean annualized new heterotopic ossification (HO) volume relative to untreated patients from a longitudinal Natural History Study (NHS).
- The Phase II CLARINET FORTE study results showed that increasing the dose frequency of Somatuline<sup>®</sup> from monthly to bi-monthly achieved a progression-free survival of 8.3 months in patients with progressive midgut neuroendocrine tumors (NETs) and 5.6 months in patients with progressive pancreatic NETs. These results showed no new safety signals associated with this increased dose regimen, potentially delaying the need for additional, more toxic second-line therapies.

## Third quarter 2020 sales highlights

Note: Unless stated otherwise, all variations in sales are stated excluding foreign exchange impacts (currency effects established by recalculating net sales for the relevant period at the exchange rates from the previous period)

(in million euros)	2020	2019	% Variation	% Variation at constant currency <sup>1</sup>
<b>Specialty Care</b>	<b>580.5</b>	<b>574.2</b>	<b>1.1%</b>	<b>5.1%</b>
Somatuline®	272.9	264.0	3.4%	7.1%
Decapeptyl®	94.5	98.9	-4.5%	-2.8%
Cabometyx®	76.8	64.5	19%	20.9%
Onivyde®	27.5	26.1	5.5%	11.0%
Other Oncology	7.4	6.5	13.4%	13.7%
Dysport®	87.4	97.4	-10.2%	-1.4%
Nutropin AQ®	8.5	10.2	-16.5%	-16.3%
Increlex®	5	5.8	-14.7%	-11.6%
Other Specialty Care	0.5	0.7	-26.7%	-12.4%
<b>Consumer Healthcare</b>	<b>52.8</b>	<b>70.6</b>	<b>-25.1%</b>	<b>-21.9%</b>
Smecta®	20.2	34.1	-40.9%	-37.7%
Forlax®	10.2	10.5	-2.4%	-0.1%
Tanakan®	7.2	8.8	-18%	-12.3%
Fortrans/Eziclen	7.2	8.3	-14.3%	-9.8%
Other Consumer Healthcare	8.1	8.8	-8.7%	-8.0%
<b>Group sales</b>	<b>633.3</b>	<b>644.7</b>	<b>-1.8%</b>	<b>2.2%</b>

**Q3 2020 Group sales** grew 2.2%<sup>1</sup> to €633.3 million.

Sales of **Specialty Care** products reached €580.5 million, up 5.1% year-on-year.

**Somatuline** sales reached €272.9 million, up 7.1% year-on-year, driven by volume growth in North America, the U.K. and Germany and despite delays in patient diagnoses and treatment due to COVID-19. In the U.S., the performance of Somatuline in Q3 was also negatively impacted by end-user buying patterns.

**Decapeptyl** sales reached €94.5 million, down 2.8% year-on-year, mainly due to lower sales in China and in some European countries as a result of the impact of COVID-19.

**Cabometyx** sales reached €76.8 million, growing 20.9% year-on-year, driven by good performance in Major Western European countries, Russia and Brazil.

**Onivyde** sales reached €27.5 million, up 11% year-on-year, driven by volume growth in the U.S.

**Dysport** sales reached €87.4 million, down 1.4% year-on-year, impacted by COVID-19 despite a gradual recovery of the therapeutics market and better dynamics in the aesthetics market.

**Consumer Healthcare** product sales reached €52.8 million, down 21.9%<sup>1</sup>, with a decrease in **Smecta** sales of 38% impacted by COVID-19, implementation of hospital central procurement in China and lower performance in France.

<sup>1</sup> 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.

## **Conference call**

Ipsen will hold a conference call Thursday, 22 October 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/3185126>

Conference ID: **3185126**

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.ipсен.com.fr](http://www.ipсен.com.fr)

## **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](http://www.ipsen.com))

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

### Sales by therapeutic area and by product

(in million euros)	3 <sup>rd</sup> Quarter				9 Months			
	2020	2019	% Variation	% Variation at constant currency <sup>1</sup>	2020	2019	% Variation	% Variation at constant currency <sup>1</sup>
Oncology	479.1	460.1	4.1%	7.2%	1,446.5	1,339.2	8.0%	8.7%
Somatuline®	272.9	264.0	3.4%	7.1%	835.1	742.9	12.4%	13.1%
Decapeptyl®	94.5	98.9	-4.5%	-2.8%	288.0	297.3	-3.1%	-2.3%
Cabometyx®	76.8	64.5	19.0%	20.9%	213.6	176.3	21.1%	22.4%
Onivyde®	27.5	26.1	5.5%	11.0%	90.0	100.5	-10.4%	-10.7%
Other Oncology	7.4	6.5	13.4%	13.7%	19.8	22.1	-10.7%	-10.7%
Neuroscience	87.9	98.0	-10.3%	-1.5%	258.4	285.8	-9.6%	-5.5%
Dysport®	87.4	97.4	-10.2%	-1.4%	256.9	283.6	-9.4%	-5.3%
Rare Diseases	13.5	16.0	-15.9%	-14.6%	42.6	49.2	-13.3%	-13.2%
Nutropin AQ®	8.5	10.2	-16.5%	-16.3%	27.7	32.1	-13.6%	-13.3%
Increlex®	5.0	5.8	-14.7%	-11.6%	14.9	17.1	-12.9%	-12.9%
Specialty Care	580.5	574.2	1.1%	5.1%	1,747.6	1,674.1	4.4%	5.7%
Smecta®	20.2	34.1	-40.9%	-37.7%	58.0	92.0	-37.0%	-35.2%
Forlax®	10.2	10.5	-2.4%	-0.1%	30.0	29.5	1.6%	2.7%
Tanakan®	7.2	8.8	-18.0%	-12.3%	26.6	26.4	1.0%	4.1%
Fortrans/Eziclen®	7.2	8.3	-14.3%	-9.8%	19.0	25.1	-24.2%	-22.4%
Other Consumer Healthcare	8.1	8.8	-8.7%	-8.0%	20.4	27.2	-25.0%	-24.7%
Consumer Healthcare	52.8	70.6	-25.1%	-21.9%	154.0	200.2	-23.1%	-21.4%
Group Sales	633.3	644.7	-1.8%	2.2%	1,901.6	1,874.3	1.5%	2.8%

### First nine months of 2020 sales highlights

**Group sales** reached €1,901.6 million, up 2.8%<sup>1</sup>, driven by Specialty Care sales growth of 5.7%<sup>1</sup>, while Consumer Healthcare sales decreased by 21.4%<sup>1</sup>.

**Specialty Care** sales amounted to €1,747.6 million, up 5.7%<sup>1</sup>. Oncology sales grew by 8.7%<sup>1</sup> while Neuroscience and Rare Diseases sales decreased by 5.5%<sup>1</sup> and 13.2%<sup>1</sup>, respectively. Over the period, the relative weight of Specialty Care reached 91.9% of total Group sales, compared to 89.3% in 2019.

In **Oncology**, sales reached €1,446.5 million, up 8.7%<sup>1</sup> year-on-year, mainly driven by the good performance of Somatuline, despite COVID-19 impacting U.S. demand, along with Cabometyx across most geographies. This was partially offset by lower Onivyde sales to Ipsen's ex-U.S. partner and lower Decapeptyl sales in China due to COVID-19. Over the period, Oncology sales represented 76.1% of total Group sales, compared to 71.5% in 2019.

**Somatuline** – Sales reached €835.1 million, up 13.1%<sup>1</sup> year-on-year, driven by a 16.9%<sup>1</sup> increase in North America from volume growth despite adverse impacts of COVID-19 on patient diagnoses and treatment. Sales performance also reflected continued market share gains in most other geographies and a limited impact from the octreotide generic launch in Europe. The performance of Somatuline in Q3 was also negatively impacted by end-user buying patterns in the U.S.

**Decapeptyl** – Sales reached €288.0 million, down 2.3%<sup>1</sup> year-on-year, mainly due to lower sales in China impacted by COVID-19 and competitive pressure despite solid volume growth in Major Western European countries and Algeria.

**Cabometyx** – Sales reached €213.6 million, up 22.4%<sup>1</sup> year-on-year, driven by strong performance across most geographies.

<sup>1</sup>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.

**Onivyde** – Sales reached €90.0 million, down 10.7%<sup>1</sup>, impacted by a significant decline in sales to Ipsen's ex-U.S. partner despite demand growth in the U.S.

In **Neuroscience**, sales of **Dysport** reached €256.9 million, down 5.3%<sup>1</sup>, impacted in most geographies by closure of treatment centers resulting from COVID-19, despite a recovery from Ipsen's aesthetics partner. Over the period, Neuroscience sales represented 13.6% of total Group sales, compared to 15.2% in 2019.

In **Rare Diseases**, sales of **Nutropin AQ** reached €27.7 million, down 13.3%<sup>1</sup> year-on-year, mainly due to lower volumes in France and Germany. Sales of **Increlex** reached €14.9 million, down 12.9%<sup>1</sup> year-on-year, mainly due to lower demand in the U.S. Over the period, Rare Diseases sales represented 2.2% of total Group sales, compared to 2.6% in 2019.

**Consumer Healthcare** sales reached €154.0 million, down 21.4%<sup>1</sup>, with a decrease in **Smecta** sales of 35.2%<sup>1</sup> impacted by COVID-19. Performance has also been impacted by the implementation of hospital central procurement in China and the lower performance in France. **Fortrans/Eziclen** sales were down 22.4%<sup>1</sup> year-on-year, mainly due to the impact of COVID-19 in China and Russia. **Tanakan** sales were up 4.1%<sup>1</sup> year-on-year, driven by positive market dynamics in Russia. Over the period, Consumer Healthcare sales represented 8.1% of total Group sales, compared to 10.7% in 2019.

### Sales by geographical area

(in million euros)	3 <sup>rd</sup> Quarter				9 Months			
	2020	2019	% Variation	% Variation at constant currency <sup>1</sup>	2020	2019	% Variation	% Variation at constant currency <sup>1</sup>
France	73.2	71.2	2.8%	2.8%	220.0	240.1	-8.4%	-8.5%
Germany	52.1	47.1	10.5%	10.5%	146.1	141.7	3.1%	3.1%
United Kingdom	28.2	25.3	11.2%	11.5%	85.6	75.9	12.8%	12.8%
Italy	21.8	27.8	-21.4%	-21.4%	82.9	87.8	-5.5%	-5.5%
Spain	26.1	26.3	-0.6%	-0.6%	81.0	77.1	5.1%	5.1%
<b>Major Western European countries</b>	<b>201.4</b>	<b>197.8</b>	<b>1.8%</b>	<b>1.9%</b>	<b>615.7</b>	<b>622.5</b>	<b>-1.1%</b>	<b>-1.1%</b>
Eastern Europe	50.9	54.7	-6.8%	2.1%	157.9	156.2	1.1%	5.6%
Others Europe	64.1	70.7	-9.4%	-7.1%	206.4	198.4	4.0%	5.4%
<b>Other European Countries</b>	<b>115.1</b>	<b>125.4</b>	<b>-8.3%</b>	<b>-3.1%</b>	<b>364.3</b>	<b>354.6</b>	<b>2.7%</b>	<b>5.5%</b>
<b>North America</b>	<b>204.5</b>	<b>196.3</b>	<b>4.2%</b>	<b>9.3%</b>	<b>623.3</b>	<b>557.3</b>	<b>11.9%</b>	<b>12.0%</b>
Asia	60.0	65.5	-8.5%	-6.6%	135.7	170.5	-20.4%	-19.5%
Other countries in the Rest of the world	52.4	59.7	-12.3%	0.3%	162.5	169.4	-4.0%	3.5%
<b>Rest of the World</b>	<b>112.4</b>	<b>125.2</b>	<b>-10.3%</b>	<b>-3.3%</b>	<b>298.2</b>	<b>339.9</b>	<b>-12.3%</b>	<b>-8.0%</b>
<b>Group Sales</b>	<b>633.3</b>	<b>644.7</b>	<b>-1.8%</b>	<b>2.2%</b>	<b>1,901.6</b>	<b>1,874.3</b>	<b>1.5%</b>	<b>2.8%</b>

Sales in **Major Western European countries** reached €615.7 million, down 1.1%<sup>1</sup> year-on-year. Over the period, sales in Major Western European countries represented 32.4% of total Group sales, compared to 33.2% in 2019.

**France** – Sales reached €220.0 million, down 8.5%<sup>1</sup> year-on-year, mainly due to lower Onivyde sales to Ipsen's ex-U.S. partner and the negative impact of COVID-19 on Consumer Healthcare products offset by continued double-digit volume growth of Cabometyx and Decapeptyl.

**Germany** – Sales reached €146.1 million, up 3.1%<sup>1</sup> year-on-year, driven by continued solid volume growth

<sup>1</sup> 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.

of Somatuline, with limited impact from the octreotide generic launch, and Cabometyx performance mainly in RCC 2L+ offset by lower Decapeptyl and Dysport demand impacted by COVID-19.

**United Kingdom** – Sales reached €85.6 million, up 12.8%<sup>1</sup> year-on-year, driven by solid performance across the Oncology portfolio.

**Italy** – Sales reached €82.9 million, down 5.5%<sup>1</sup> year-on-year, due to lower sales of Consumer Healthcare and oncology products impacted by COVID-19.

**Spain** – Sales reached €81.0 million, up 5.1%<sup>1</sup> year-on-year, driven by the growth of Cabometyx, Somatuline and Decapeptyl with continued market share gains despite COVID-19.

Sales in **Other European countries** reached €364.3 million, up 5.5%<sup>1</sup> year-on-year, driven by the performance of Cabometyx and the growth of Somatuline in several countries including Poland and Russia. Over the period, sales in the region represented 19.2% of total Group sales, compared to 18.9% in 2019.

Sales in **North America** reached €623.3 million, up 12.0%<sup>1</sup> year-on-year, driven by continued strong demand for Somatuline and steady growth of Onivyde despite the negative COVID-19 impact. This was offset by lower Dysport sales which were impacted by COVID-19 in both the aesthetics and therapeutics markets. Over the period, sales in North America represented 32.8% of total Group sales, compared to 29.7% in 2019.

Sales in the **Rest of the World** reached €298.2 million, down 8.0%<sup>1</sup> year-on-year, driven by the negative impact of COVID-19 affecting mainly Smecta and Decapeptyl in China. Rest of the World sales performance was also impacted by lower sales of Dysport in both aesthetics and therapeutics markets in the Middle East, despite higher sales in Brazil and early approval in China for the aesthetics market. This was partly offset by the good performance of Somatuline and Cabometyx across most geographies. Over the period, sales in the Rest of the World represented 15.7% of total Group sales, compared to 18.1% in 2019.

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<sup>1</sup> 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.