

## Ipsen: sales in the 3<sup>rd</sup> quarter and first nine months of 2015

- **Group sales up 5.2%<sup>1</sup> in the third quarter**
  - Specialty care sales up 8.6%<sup>1</sup>, driven by Somatuline<sup>®</sup> growth in neuroendocrine tumors
  - Primary care sales down 5.0%<sup>1</sup>, in a challenging environment in France and emerging markets
- **2015 objectives confirmed**

Paris (France), 29 October 2015 - Ipsen (Euronext: IPN; ADR: IPSEY) today reported its sales for the third quarter and first nine months of 2015.

### Third quarter and first nine months 2015 unaudited IFRS consolidated sales

(in million euros)	3 <sup>rd</sup> quarter				9 months			
	2015	2014	% Variation	% Variation at constant currency	2015	2014	% Variation	% Variation at constant currency
<b>Specialty care</b>	<b>275.6</b>	<b>245.7</b>	<b>12.2%</b>	<b>8.6%</b>	<b>824.5</b>	<b>718.2</b>	<b>14.8%</b>	<b>10.9%</b>
of which Somatuline <sup>®</sup>	103.4	74.3	39.2%	33.7%	291.6	213.6	36.6%	30.7%
of which Decapeptyl <sup>®</sup>	81.6	82.9	-1.6%	-6.3%	250.8	243.4	3.0%	-1.6%
of which Dysport <sup>®</sup>	68.2	66.7	2.3%	1.5%	208.8	195.3	6.9%	5.2%
<b>Primary care*</b>	<b>78.9</b>	<b>83.3</b>	<b>-5.4%</b>	<b>-5.0%</b>	<b>243.8</b>	<b>249.5</b>	<b>-2.3%</b>	<b>-4.1%</b>
of which Smecta <sup>®</sup>	26.7	33.8	-21.0%	-22.8%	89.1	94.6	-5.8%	-11.2%
of which Tanakan <sup>®</sup>	12.8	16.4	-21.8%	-12.5%	37.0	47.5	-22.3%	-15.8%
of which Forlax <sup>®</sup>	10.0	9.5	5.2%	3.2%	28.8	28.3	1.5%	-0.3%
<b>Group sales</b>	<b>354.5</b>	<b>329.0</b>	<b>7.7%</b>	<b>5.2%</b>	<b>1068.3</b>	<b>967.7</b>	<b>10.4%</b>	<b>7.0%</b>

\* Drug-related sales (active ingredients and raw materials) are recorded within Primary care sales

Commenting on the third quarter 2015 performance, **Marc de Garidel, Chairman and Chief Executive Officer of Ipsen** said: “Specialty care remains our main growth driver thanks to the successful launch of Somatuline<sup>®</sup> in neuroendocrine tumors in the US and Europe and the growth of Dysport<sup>®</sup>, notably in the aesthetic indication. Moreover, the challenging environment in emerging markets, especially in China, is still adversely affecting the performance of Decapeptyl<sup>®</sup> and of the primary care.” **Marc de Garidel** added: “We are pleased with the positive Phase 3 results for telotristat etiprate released early August, which are an important milestone in our strategy to become global leaders in neuroendocrine tumors”.

<sup>1</sup> Year-on-year growth excluding foreign exchange impacts

## **Review of the third quarter 2015:**

*Note: Unless stated otherwise, all variations in sales are stated excluding foreign exchange impacts.*

**Consolidated Group sales** grew 5.2% to €354.5 million, driven by the performance of specialty care.

**Specialty care** products reached €275.6 million, up 8.6% year-on-year, supported by the strong growth of Somatuline<sup>®</sup>, up 33.7% year-on-year.

**Somatuline<sup>®</sup>** sales reached €103.4 million, up 33.7% year-on-year, driven by strong growth in North America following the launch of the new indication in neuroendocrine tumors at the beginning of the year, and by a good overall performance in Europe, notably in Germany, Italy and France.

**Decapeptyl<sup>®</sup>** sales reached €81.6 million, down 6.3% year-on-year, affected by sales decrease in China in the context of a market slowdown and pricing pressure in some provinces, as well as further contraction of the European pharmaceutical market impacted by additional price reductions.

**Dysport<sup>®</sup>** sales reached €68.2 million, up 1.5% year-on-year, driven by the solid performance of the aesthetic indication, notably in Russia, Brazil, Mexico and Australia, yet affected by an unfavorable base effect in the United States arising from the exceptional orders in aesthetics placed by Valeant and taken over by Galderma following the agreement signed between Ipsen and Galderma in July 2014.

**Primary care** products reached €78.9 million, down 5.0% year-on-year, affected by sales decline of Smecta<sup>®</sup> in China and of Tanakan<sup>®</sup> in Russia.

**Smecta<sup>®</sup>** sales reached €26.7 million, down 22.8% year-on-year, affected by sales decrease in China due to an unfavorable inventory effect in the distribution channel during the second and third quarters and pricing pressure in some regions, as well as the termination of direct sales in Algeria (where Ipsen now supplies the active ingredient instead of the finished product) and sales decrease in Vietnam (where the majority of sales in the period were anticipated in the first quarter ahead of the import license renewal).

**Tanakan<sup>®</sup>** sales reached €12.8 million euros, down 12.5% year-on-year, impacted by a market slowdown in France and in Russia.

**Forlax<sup>®</sup>** sales reached €10.0 million, up 3.2% year-on-year, driven by the performance in Algeria and in Russia, despite a sales decline in France, penalized by the “Tiers-Payant<sup>1</sup>” regulation.

## **2015 objectives confirmed**

As a result of the good performance of Somatuline<sup>®</sup> and despite the slowdown in emerging markets, Ipsen confirms its 2015 objectives<sup>2</sup>:

- Specialty care sales growth at or above 14.0% year-on-year
- Primary care sales decline between -3.0% and 0.0% year-on-year
- Core Operating margin at or above 22.0% of Group sales

<sup>1</sup> With the “Tiers-Payant” regulation, the patient now pays upfront for a branded drug and is reimbursed only later on

<sup>2</sup> Sales objectives are set at constant currency and drug-related sales (active substances and raw materials) are from now on recorded in the Primary Care sales line

## **About Ipsen**

Ipsen is a global specialty-driven biotechnological group with total sales exceeding €1.2 billion in 2014. Ipsen sells more than 20 drugs in more than 115 countries, with a direct commercial presence in 30 countries. Ipsen's ambition is to become a leader in specialty healthcare solutions for targeted debilitating diseases. Its development strategy is supported by 3 franchises: neurology, endocrinology and urology-oncology. Ipsen's commitment to oncology is exemplified through its growing portfolio of key therapies improving the care of patients suffering from prostate cancer, bladder cancer and neuro-endocrine tumors. Ipsen also has a significant presence in primary care. Moreover, the Group has an active policy of partnerships. Ipsen's R&D is focused on its innovative and differentiated technological platforms, peptides and toxins, located in the heart of the leading biotechnological and life sciences hubs (Les Ulis, France; Slough/Oxford, UK; Cambridge, US). In 2014, R&D expenditure totaled close to €187 million, representing about 15% of Group sales. The Group has more than 4,500 employees worldwide. Ipsen's shares are traded on segment A of Euronext Paris (stock code: IPN, ISIN code: FR0010259150) and eligible to the "Service de Règlement Différé" ("SRD"). The Group is part of the SBF 120 index. Ipsen has implemented a Sponsored Level I American Depositary Receipt (ADR) program, which trade on the over-the-counter market in the United States under the symbol IPSEY. For more information on Ipsen, visit [www.ipсен.com](http://www.ipсен.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 favourable 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 2014 Registration Document available on its website ([www.ipsen.com](http://www.ipsen.com)).

**For further information:**

**Media**

**Didier Véron**

Senior Vice-President, Public Affairs  
and Communication

Tel.: +33 (0)1 58 33 51 16

Fax: +33 (0)1 58 33 50 58

E-mail: [didier.veron@ipsen.com](mailto:didier.veron@ipsen.com)

**Brigitte Le Guennec**

Corporate External Communication

Tel.: +33 (0)1 58 33 51 17

Fax: +33 (0)1 58 33 50 58

E-mail : [brigitte.le.guennec@ipsen.com](mailto:brigitte.le.guennec@ipsen.com)

**Financial Community**

**Stéphane Durant des Aulnois**

Vice-President, Investor Relations

Tel.: +33 (0)1 58 33 60 09

Fax: +33 (0)1 58 33 50 63

E-mail: [stephane.durant.des.aulnois@ipsen.com](mailto:stephane.durant.des.aulnois@ipsen.com)

**Côme de La Tour du Pin**

Investor Relations Manager

Tel.: +33 (0)1 58 33 53 31

Fax: +33 (0)1 58 33 50 63

E-mail: [come.de.la.tour.du.pin@ipsen.com](mailto:come.de.la.tour.du.pin@ipsen.com)

## Comparison of consolidated sales for the third quarter and first nine months 2015 and 2014:

### Sales by therapeutic area and by product

Note: Unless stated otherwise, all variations in sales are stated excluding foreign exchange impacts.

The following table shows sales by therapeutic area and by product for the third quarters and first nine months 2015 and 2014:

(in millions euros)	3 <sup>rd</sup> Quarter				9 months			
	2015	2014	% Variation	% Variation at constant currency	2015	2014	% Variation	% Variation at constant currency
Urology-oncology	85.7	86.7	-1.1%	-5.6%	263.7	255.5	3.2%	-1.2%
of which Hexvix <sup>®</sup>	4.1	3.8	9.7%	9.1%	12.9	12.1	6.7%	6.0%
of which Decapeptyl <sup>®</sup>	81.6	82.9	-1.6%	-6.3%	250.8	243.4	3.0%	-1.6%
Endocrinology	121.4	92.0	31.9%	27.0%	351.2	267.1	31.5%	26.3%
of which Somatuline <sup>®</sup>	103.4	74.3	39.2%	33.7%	291.6	213.6	36.6%	30.7%
of which NutropinAq <sup>®</sup>	13.9	14.2	-2.7%	-3.3%	45.5	45.1	0.9%	0.2%
of which Increlex <sup>®</sup>	4.1	3.5	18.1%	4.6%	14.0	8.5	65.6%	49.7%
Neurology	68.5	67.0	2.3%	1.6%	209.6	195.6	7.2%	5.5%
of which Dysport <sup>®</sup>	68.2	66.7	2.3%	1.5%	208.8	195.3	6.9%	5.2%
<b>Specialty care</b>	<b>275.6</b>	<b>245.7</b>	<b>12.2%</b>	<b>8.6%</b>	<b>824.5</b>	<b>718.2</b>	<b>14.8%</b>	<b>10.9%</b>
Gastroenterology	53.6	56.1	-4.5%	-6.7%	167.4	166.7	0.4%	-4.4%
of which Smecta <sup>®</sup>	26.7	33.8	-21.0%	-22.8%	89.1	94.6	-5.8%	-11.2%
of which Forlax <sup>®</sup>	10.0	9.5	5.2%	3.2%	28.8	28.3	1.5%	-0.3%
Cognitive disorders	12.8	16.4	-21.8%	-12.5%	37.0	47.5	-22.3%	-15.8%
of which Tanakan <sup>®</sup>	12.8	16.4	-21.8%	-12.5%	37.0	47.5	-22.3%	-15.8%
Cardiovascular	3.9	3.8	3.0%	3.0%	13.4	15.1	-11.6%	-11.9%
Other Primary Care	2.3	2.6	-10.0%	-9.3%	7.8	8.3	-6.1%	-6.0%
Drug-related Sales	6.2	4.4	39.6%	38.5%	18.3	11.8	55.4%	54.5%
<b>Primary care*</b>	<b>78.9</b>	<b>83.3</b>	<b>-5.4%</b>	<b>-5.0%</b>	<b>243.8</b>	<b>249.5</b>	<b>-2.3%</b>	<b>-4.1%</b>
<b>Group Sales</b>	<b>354.5</b>	<b>329.0</b>	<b>7.7%</b>	<b>5.2%</b>	<b>1068.3</b>	<b>967.7</b>	<b>10.4%</b>	<b>7.0%</b>

\* Drug-related sales (active ingredients and raw materials) are recorded within Primary care sales.

In the third quarter, sales have reached €354.5 million, up 5.2% year-on-year, driven by specialty care sales growth of 8.6% despite primary care sales decline of 5.0%. In the first nine months 2015, sales amounted to €1 068.3 million, up 7.0% year-on-year.

In the third quarter 2015, sales of **Specialty care** products reached €275.6 million, up 8.6% year-on-year. In the first nine months 2015, sales amounted to €824.5 million, up 10.9%. Sales in urology-oncology were down 1.2% while sales in endocrinology and neurology grew by respectively 26.3% and 5.5%. The relative weight of specialty care products continued to increase to reach 77.2% of total Group sales, compared to 74.2% the previous year.

In **Urology-oncology**, sales of **Decapeptyl<sup>®</sup>** reached €81.6 million in the third quarter 2015, down 6.3% year-on-year, affected by sales decrease in China in the context of a market slowdown and pricing pressure in some provinces. In the first nine months 2015, sales amounted to €250.8 million, down 1.6%, affected by the slowdown in China as well as the contraction of the European pharmaceutical market with a more

frequent use of co-payment in Southern Europe and additional price reductions, notably an 11.0% cut as of 1<sup>st</sup> January 2015 in Greece and a 3.0% cut as of 1<sup>st</sup> February 2015 in France and more than 20% in Algeria. In the first nine months 2015, sales of **Hexvix**<sup>®</sup> amounted to €12.9 million, up 6.0% compared to the previous year, mostly driven by the performance in France and Germany. Germany represented around 70% of total product sales. Over the period, sales in Urology-oncology represented 24.7% of total Group sales, compared to 26.4% the previous year.

In **Endocrinology**, sales reached €121.4 million in the third quarter 2015, up 27.0% year-on-year. In the first nine months 2015, sales amounted to €351.2, up 26.3%, representing 32.9% of total Group sales, compared to 27.6% the previous year.

**Somatuline**<sup>®</sup> – In the third quarter 2015, sales reached €103.4 million, up 33.7% year-on-year. In the first nine months 2015, sales of Somatuline<sup>®</sup> grew 30.7%, driven by strong growth in North America following the launch of the new indication of neuroendocrine tumors at the beginning of the year. The product also registered good performance in Europe, notably in Germany, the UK, Spain and France.

**NutropinAq**<sup>®</sup> – In the third quarter 2015, sales reached €13.9 million, down 3.3% year-on-year. In the first nine months 2015, sales of NutropinAq<sup>®</sup> amounted to €45.5 million, up 0.2%, compared to 2014.

**Increlex**<sup>®</sup> – In the third quarter 2015, sales reached €4.1 million, up 4.6% year-on-year. In the first nine months 2015, sales of Increlex<sup>®</sup> amounted to €14.0 million, up 49.7% year-on-year, boosted by a favorable base effect related to the shortage which started mid-June 2013 in the United States and in August 2013 in Europe. Supply gradually resumed in Europe in early 2014 and in the United States in June 2014.

In **Neurology**, **Dysport**<sup>®</sup> sales reached €68.2 million in the third quarter 2015, up 1.5% year-on-year, affected by an unfavorable base effect in the United States related to exceptional orders in the aesthetic segment placed by Valeant and taken over by Galderma following the agreement signed between Ipsen and Galderma in July 2014. In the first nine months 2015, sales amounted to €208.8 million, up 5.2%, driven by the solid performance in the aesthetic indication, notably in Russia, Brazil, Mexico and Australia. Over the period, Neurology sales represented 19.6% of total Group sales, compared to 20.2% a year earlier.

In the third quarter 2015, sales of **Primary care** products reached €78.9 million, down 5.0% year-on-year, affected by Smecta<sup>®</sup> sales decrease in China, in Algeria (where Ipsen now supplies the active ingredient of Smecta<sup>®</sup> instead of the finished product) and in Vietnam (where the majority of sales in the period were anticipated in the first quarter ahead of the import license renewal), as well as by Tanakan<sup>®</sup> sales decrease in Russia. In the first nine months 2015, sales amounted to €243.8 million, down 4.1% year-on-year. In France, sales of primary care were down 7.8%, penalized by the 7.5% price cut on Smecta<sup>®</sup> in July 2014 and by the continued erosion of Tanakan<sup>®</sup> sales. Internationally, sales decreased 2.9%, affected by sales decline in China and Russia, notably on Smecta<sup>®</sup> and Tanakan<sup>®</sup>. Primary care sales in France accounted for 24.9% of the Group's total primary care sales, compared to 26.3% the previous year.

In **Gastroenterology**, sales reached €53.6 million in the third quarter 2015, down 6.7% year-on-year. In the first nine months 2015, sales amounted to €167.4 million euros, down 4.4% year-on-year.

**Smecta**<sup>®</sup> – In the third quarter 2015, sales reached €26.7 million, down 22.8% year-on-year. In the first nine months 2015, sales amounted to €89.1 million euros, down 11.2% year-on-year, affected by sales decrease in China due to an unfavorable inventory effect in the distribution channel during the second and third quarters in a context of pricing pressure in some regions, as well as the termination of direct sales in Algeria. Sales were also affected in France by the price cut implemented in July 2014.

**Forlax**<sup>®</sup> – In the third quarter 2015, sales reached €10.0 million, up 3.2% year-on-year, driven by the performance in Algeria and in Russia, despite a sales decline in France, penalized by the

“Tiers-Payant<sup>1</sup>” regulation. In the first nine months 2015, sales amounted to €28.8 million euros, down 0.3% year-on-year.

In the **cognitive disorders area**, sales of **Tanakan<sup>®</sup>** reached €12.8 million euros in the third quarter 2015, down 12.5% year-on-year. Sales in the first nine months 2015 amounted to €37.0 million euros, down 15.8%, impacted by a market slowdown in France and in Russia.

**In the cardiovascular area**, sales reached €3.9 million euros in the third quarter 2015, up 3.0% year-on-year. In the first nine months 2015, sales amounted to €13.4 million euros, down 11.9%, mainly impacted by the decline of **Nisis<sup>®</sup> / Nisisco<sup>®</sup>** sales, hit by an additional 40.0% price cut in February 2015 in France.

Sales of **Other primary care** products reached €2.3 million in the third quarter 2015, down 9.3% year-on-year, mainly affected by the 19.1% decline in **Adrovanse<sup>®</sup>** sales over the period. In the first nine months 2015, sales amounted to €7.8 million, down 6.0%.

In the third quarter 2015, **Drug-related sales (active ingredients and raw materials)** reached €6.2 million, up 38.5% year-on-year. In the first nine months 2015, sales amounted to €18.3 million euros, up 54.5%. This performance is mainly explained by the new business model in Algeria where Ipsen now supplies the active ingredient of Smecta<sup>®</sup> to a local manufacturer and records sales in Drug-related sales, the good performance of the supply of Gingko Biloba extracts to Schwabe Group’s partner, and the sales resumption of Smecta<sup>®</sup>’s active ingredient in South Korea.

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<sup>1</sup> With the “Tiers-Payant” regulation, the patient now pays upfront for a branded drug and is reimbursed only later on

## Sales by geographical area

Group sales by geographical area in the third quarters and first nine months 2015 and 2014 were as follows:

(in million euros)	3 <sup>rd</sup> Quarter				9 months			
	2015	2014	% Variation	% Variation at constant currency	2015	2014	% Variation	% Variation at constant currency
France	51.6	51.4	0.5%	0.5%	158.5	158.0	0.3%	0.3%
United Kingdom	19.4	16.9	15.1%	3.5%	56.5	47.2	19.6%	7.0%
Spain	15.5	15.1	2.4%	2.4%	48.1	44.3	8.5%	8.5%
Germany	26.9	23.4	15.0%	14.9%	80.4	70.5	14.0%	14.0%
Italy	18.0	17.0	5.8%	5.8%	60.0	60.8	-1.3%	-1.3%
<b>Major Western European countries</b>	<b>131.5</b>	<b>123.8</b>	<b>6.2%</b>	<b>4.6%</b>	<b>403.5</b>	<b>380.9</b>	<b>5.9%</b>	<b>4.4%</b>
Eastern Europe	40.3	43.4	-7.0%	10.5%	124.4	134.0	-7.2%	6.0%
Others Europe	39.6	35.8	10.7%	8.9%	116.2	110.1	5.5%	5.2%
<b>Other European Countries</b>	<b>79.9</b>	<b>79.1</b>	<b>1.0%</b>	<b>9.7%</b>	<b>240.6</b>	<b>244.2</b>	<b>-1.5%</b>	<b>5.6%</b>
<b>North America</b>	<b>41.8</b>	<b>26.4</b>	<b>58.1%</b>	<b>31.6%</b>	<b>109.2</b>	<b>57.9</b>	<b>88.6%</b>	<b>55.6%</b>
Asia	54.7	52.3	4.7%	-10.6%	171.5	144.5	18.7%	-0.8%
Other countries in the Rest of the world	46.5	47.4	-1.9%	2.8%	143.4	140.2	2.3%	2.1%
<b>Rest of the World</b>	<b>101.3</b>	<b>99.7</b>	<b>1.6%</b>	<b>-4.9%</b>	<b>315.0</b>	<b>284.7</b>	<b>10.6%</b>	<b>0.5%</b>
<b>Group Sales</b>	<b>354.5</b>	<b>329.0</b>	<b>7.7%</b>	<b>5.2%</b>	<b>1068.3</b>	<b>967.7</b>	<b>10.4%</b>	<b>7.0%</b>

In the third quarter 2015, sales generated in the **Major Western European countries** reached €131.5 million, up 4.6% year-on-year. In the first nine months 2015, sales amounted to €403.5 million, up 4.4%. Sales in the Major Western European countries represented 37.8% of total Group sales in the first nine months 2015, compared to 39.4% the previous year.

**France** – In the third quarter 2015, sales reached €51.6 million, slightly up 0.5% year-on-year. In the first nine months 2015, sales amounted to €158.5 million, stable year-on-year. Sales of specialty care products, up 6.0% over the period, were driven by the sustained growth of Somatuline<sup>®</sup> and Dysport<sup>®</sup> but partially offset by the decrease in Decapeptyl<sup>®</sup> sales, following the 3.0% price cut implemented as of 1<sup>st</sup> February 2015. Sales of primary care continued declining, affected by Tanakan<sup>®</sup> performance and the price cut on Smecta<sup>®</sup>. The relative weight of France in the Group's consolidated sales has continued to decrease and now represents 14.8% of sales, compared to 16.3% the previous year.

**Germany** – In the third quarter 2015, sales reached €26.9 million, up 14.9% year-on-year. In the first nine months 2015, sales reached €80.4 million, up 14.0%, driven by the strong growth of Somatuline<sup>®</sup> and Hexvix<sup>®</sup>, offsetting the decline in Dysport<sup>®</sup> sales due to a more competitive environment. Over the period, sales in Germany represented 7.5% of total Group sales, compared to 7.3% a year before.

**Italy** – In the third quarter 2015, sales reached €18.0 million, up 5.8% year-on-year. In the first nine months 2015, sales reached €60.0 million, down 1.3%, affected by the implementation of austerity measures targeting hospital products. In the first nine months 2015, sales in Italy represented 5.6% of consolidated Group sales, compared to 6.3% the previous year.

**United Kingdom** – In the third quarter 2015, sales reached €19.4 million, up 3.5% year-on-year. In the first nine months 2015, sales amounted to €56.5 million, up 7.0%, supported by the strong growth of Somatuline<sup>®</sup> and Decapeptyl<sup>®</sup>. Over the period, sales in the United Kingdom represented 5.3% of total Group sales, compared to 4.9% the previous year.

**Spain** – In the third quarter 2015, sales reached €15.5 million, up 2.4% year-on-year. In the first nine months 2015, sales amounted to €48.1 million, up 8.5%, driven by the double-digit growth of

Somatuline<sup>®</sup> and Decapeptyl<sup>®</sup>. In the first nine months 2015, Spain accounted for 4.5% of total Group sales, compared to 4.6% the previous year.

In the third quarter 2015, sales generated in the **Other European countries** reached €79.9 million, up 9.7% year-on-year. In the first nine months 2015, sales amounted to €240.6 million, up 5.6% year-on-year, supported by the good performance of Dysport<sup>®</sup> in Russia and that of Somatuline<sup>®</sup> in Eastern and Western Europe (ex-Major Western European countries<sup>1</sup>). Nevertheless, sales were impacted by the contraction of the Group's activities in Ukraine, as a consequence of the ongoing political crisis. Over the period, sales in this region represented 22.5% of consolidated Group sales, compared to 25.2% the previous year.

In the third quarter 2015, sales generated in **North America** reached €41.8 million, up 31.6% year-on-year, supported by the acceleration of Somatuline<sup>®</sup> growth, despite the unfavourable base effect related to Galderma's exceptional aesthetics orders in the third quarter 2014. In the first nine months 2015, sales amounted to €109.2 million, up 55.6% year-on-year, mainly driven by strong Somatuline<sup>®</sup> growth following the launch of the new indication in the treatment of neuroendocrine tumors. Sales in North America represented 10.2% of consolidated Group sales, compared to 6.0% a year before.

In the third quarter 2015, sales generated in the **Rest of the World** reached €101.3 million, down 4.9% year-on-year, affected by Decapeptyl<sup>®</sup> and Smecta<sup>®</sup> performance in China and Algeria, partially offset by Dysport<sup>®</sup>'s good performance in Australia and Brazil. In the first nine months 2015, sales amounted to €315.0 million, up 0.5% year-on-year. Sales in the Rest of the World represent 29.5% of total consolidated Group sales, stable ratio over the period.

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<sup>1</sup> France, Germany, Italy, United Kingdom, Spain

## GOVERNMENT MEASURES

In the current context of financial and economic crisis, the governments of many countries in which the Group operates continue to introduce new measures to reduce public health expenses, some of which have affected the Group sales and profitability in the first nine months 2015. In addition, certain measures introduced in 2014 have continued to affect the Group's accounts year-on-year.

### Measures impacting the first nine months 2015

#### In the Major Western European countries:

- In France, all Decapeptyl<sup>®</sup> formulations were impacted by a 3.1% price decrease imposed by Public Health Authorities, in February 2015;
- In Spain, Dysport<sup>®</sup> was included in the reference price system as the product has been on the market for more than 10 years;

#### In the Other European countries:

- In Belgium, requirement for pharmaceutical companies to implement modulated price decreases on their product portfolio has been cancelled. Dysport<sup>®</sup> was subject to a mandatory price cut of 2.4% in January 2015 because the product had been reimbursed for more than 15 years. All formulations of Somatuline<sup>®</sup> were subject to a mandatory price cut of 17% as of July 1<sup>st</sup>, 2015 as the product has been reimbursed for between 12 and 15 years;
- In the Netherlands, as of 1 April and 1 October 2015, prices of Ipsen's specialty care products (excluding Hexvix<sup>®</sup> and Increlex<sup>®</sup>) increased following an International Reference Pricing review;
- In Poland, Ipsen received positive assessment results from National HTA agency on Hexvix<sup>®</sup> reimbursement application. The price is under negotiation with the Ministry of Health. Somatuline<sup>®</sup>, Decapeptyl<sup>®</sup> and Dysport<sup>®</sup> prices will be reviewed based on the lowest prices in Europe. Prices are expected to be published in January 2016;
- In Italy, as of August 1<sup>st</sup>, 2015, Decapeptyl<sup>®</sup> 3.75mg and 11.25mg were withdrawn from the pay-back procedure, meaning that the official prices were consequently decreased by 5.0%.

#### In the Rest of the World:

- In the United States, Somatuline<sup>®</sup> prices increased on 30 June and 30 September 2015 (Somatuline<sup>®</sup> 120mg: +1.6% in June, Somatuline<sup>®</sup> 60mg/90mg: +3.0% and +5.0%, respectively in June and September). Increlex<sup>®</sup> price increased 14.9% in September 2015;
- In Brazil, Dysport<sup>®</sup> therapeutics and Somatuline<sup>®</sup> prices increased 5% in April 2015 due to inflation;
- In Algeria, in the context of continuous and sharp oil price drop, the authorities are looking at drastically reducing importation cost. This applies to import of Pharmaceuticals, which stands roughly for €3 billion in the state budget. For Ipsen primary care portfolio, this also coincides with the price reduction usually assorted to the 5-year Free Sales Certificate renewal. On the specialty care segment, this resulted in a 5% price reduction for Somatuline<sup>®</sup> and of more than 20% for Decapeptyl<sup>®</sup>, as authorities were systematically benchmarking prices versus that prevailing in neighboring countries and other European countries;

Furthermore, and still in the context of the financial and economic crisis, governments of many countries in which the Group operates continue to introduce new measures to reduce public health expenses, some of which will affect the Group sales and profitability beyond 2015.

## Measures impacting beyond 2015

### In the Major Western European countries:

- In France, the government presented the new Social Security Finance Bill (PLFSS), which sets forth expenditure targets in the healthcare sector for 2015. The target growth of healthcare expenditure has been set at 2.1% year-on-year, down from 2.4% in 2014. This is expected to result in €3.2 billion savings. Moreover, the two Smecta<sup>®</sup> price cuts will fully impact countries that reference French prices (incl. European Union and North Africa) starting in 2015.

### In the Rest of the World:

- In Australia, as of December 1<sup>st</sup>, 2015, the price of NutropinAq<sup>®</sup> will be decreased by 16.0% to stay competitive as all the different brands of Somatropin are considered equivalent on a per milligram basis.
- In Algeria, part of the 2015 cost containment measures undertaken by the Authorities aim at reducing importation cost. For pharmaceuticals, a new importation quota is currently being implemented to target imported products with at least one generic that is locally manufactured. Moreover, the Economic Committee of the Ministry of Health announced its intention to strengthen transparency and increase visibility in drug pricing mechanism. It is set to implement an international price referencing (IRP) system with a basket of 9 reference countries<sup>1</sup> with FOB (« Free on Board ») price to be 10% lower than the lowest price of the benchmarked countries. The new rule is expected to be implemented as from January 2016.
- In China, an ongoing healthcare reform aims at aligning the patient management model with European standards. This results in an acceleration of hospital tenders and the implementation of a more efficient retail pharmacy distribution channel. In particular, this reform aims at removing price caps for most medicines to allow the market to play a bigger role in fixing prices. For drugs sold through retail pharmacy channels, this reform will bring more flexible drug pricing to pharmaceutical companies to raise their incentive for innovation. Yet, prices at hospital level remain subject to highly competitive bidding processes.

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<sup>1</sup> France, Belgium, Turkey, Greece, Spain, UK, Tunisia, Morocco and the country of origin

## MAJOR DEVELOPMENTS

During the first nine months of 2015, major developments included:

- On 26 January 2015 – Ipsen announced topline results for two double-blind phase III studies of Dysport® (abobotulinumtoxinA) in Pediatric Lower Limb (PLL) spasticity in children with cerebral palsy and in Adult Lower Limb (ALL) spasticity in patients who had experienced a stroke or traumatic brain injury. In the PLL phase III study, conducted in children with hemiparetic or diplegic cerebral palsy, treatment with Dysport® showed a statistically significant response versus placebo in the improvement of muscle tone, as measured by the Modified Ashworth Scale (MAS; primary endpoint), and a statistically significant overall benefit versus placebo, as measured by the Physician Global Assessment (PGA; first secondary endpoint). In the ALL phase III study, conducted in hemiparetic patients who had experienced a stroke or traumatic brain injury, treatment with Dysport® at the dose of 1500U showed a statistically significant response versus placebo in the improvement of muscle tone, as measured by the Modified Ashworth Scale (MAS; primary endpoint). An overall benefit (measured by the Physician Global Assessment (PGA); first secondary endpoint) versus placebo was observed but did not reach statistical significance according to the pre-specified statistical analysis.
- On 23 February 2015 – Ipsen Canbex Therapeutics Ltd (Canbex) announced that Canbex has granted Ipsen an option giving Ipsen the exclusive right to purchase 100% of Canbex shares upon completion of the Phase IIa study of Canbex's lead candidate for the treatment of spasticity in people with multiple sclerosis (MS), known as VSN16R. Canbex is a spin-off of University College London (UCL) that raised a Series A financing of GBP 2.3 million in 2013 from MS Ventures (the corporate venture arm of Merck Serono, Merck KGaA), the Wellcome Trust and UCL Business Plc. Under the financial terms of the agreement, Ipsen has paid an option fee of €6 million to Canbex. If Ipsen elects to exercise its option to acquire Canbex at the end of the proof of concept Phase IIa study, Canbex's shareholders will be eligible to receive a total of up to an additional €90 million, comprising an acquisition payment, and additional milestone payments contingent upon launch subsequent to achievement of clinical and regulatory success. In addition, Canbex shareholders will be eligible to receive royalties on world-wide annual net sales of VSN16R.
- On 2 March 2015 – Ipsen announced that Dominique Laymand has been appointed Senior Vice President, Chief Ethics and Compliance Officer for the Ipsen group, effective as of 16th of March. She will report directly to Marc de Garidel, Chairman and CEO of Ipsen. Dominique Laymand will be a member of the Chairman's Committee.
- On 1 April 2015 – Ipsen announced the inauguration of its new R&D center, Ipsen Bioscience, in Cambridge (MA, USA), a recognized hub in the USA for biomedical research & innovation. Ipsen's strategic decision to invest in the Ipsen Bioscience facility in Cambridge is an important element of the company's open innovation strategy and its goal of broadening its partnerships with the American biotechnology, medical and scientific communities.
- On 16 April 2015 – Active Biotech and Ipsen announced top line results of the 10TASQ10 study. While the study showed that tasquinimod reduced the risk of radiographic cancer progression or death compared to placebo (rPFS, HR=0.69, CI 95%: 0.60 – 0.80) in patients with metastatic castration resistant prostate cancer (mCRPC) who have not received chemotherapy, tasquinimod did not extend overall survival (OS, HR=1.09, CI 95%: 0.94 – 1.28). Efficacy results together with preliminary safety data do not support positive benefit risk balance in this population. Therefore the companies have decided to discontinue all studies in prostate cancer. Full results will be presented at an upcoming scientific conference.
- On 19 May 2015 – Ipsen announced the signature of an agreement to acquire OctreoPharm Sciences (referred to as OctreoPharm), a private German life sciences company focusing on the development of innovative radioactive labeled compounds for molecular imaging diagnostics and therapeutic applications. Ipsen plans to maintain the company location and staff to ensure successful transition of know-how and expertise. Ipsen expects to complete its acquisition once closing conditions have been cleared. Under the terms of the agreement, which is subject to closing conditions, OctreoPharm's shareholders are eligible to receive up to a total of approximately €50 million for the purchase of 100% of the company's shares in the form of an upfront payment and downstream payments contingent upon clinical and regulatory milestones.

- On 2 June 2015 – Ipsen confirmed its eligibility for the PEA-PME scheme, in accordance with the French decree n° 2014-283 of 4 March 2014. The Group complies with the thresholds set by the legislator for eligibility to the PEA-PME scheme, namely having less than 5 000 employees and total revenue below €1 500 million or total assets below €2 000 million. As a consequence, investment in company shares can be made through PEA-PME accounts, benefiting from the same tax advantages as the traditional Equity Savings Plan (PEA).
- On 3 June 2015 – Ipsen announced it has granted Natixis a mandate to purchase 500 000 shares, or about 0.60% of the share capital. This mandate begins on 3 June 2015 and will end on 31 December 2015. The purchased shares will be cancelled, mainly to compensate for the dilution resulting from the issuance of new shares within the free share plans. These operations are part of the authorizations granted by the Combined Shareholder's meeting held on 27 May 2015.
- On 2 July 2015 - Ipsen hosted its Investor Day. The Group's management provided a comprehensive review of its 2020 strategy and its 2020 outlook including organic sales ranging between €1.8bn and €2bn and Core Operating Margin of above 26%.
- On 16 July 2015 – Ipsen announced that the U.S. Food and Drug Administration (FDA) has approved its supplemental Biologics License Application (sBLA) for Dysport® (abobotulinumtoxinA) for the treatment of upper limb spasticity in adult patients after the submission of the dossier in September 2014. Dysport® is now approved for the treatment of upper limb spasticity in adult patients, to decrease the severity of increased muscle tone in elbow flexors, wrist flexors and finger flexors. Clinical improvement may be expected one week after administration of Dysport®. A majority of patients in clinical studies were retreated between 12 and 16 weeks; some patients had a duration of response as long as 20 weeks. In Europe, regulatory procedures are in progress for strengthening the existing upper limb spasticity label indication of Dysport® to include key medical data such as muscle dose recommendations, treatment intervals, efficacy data and safety updates.
- On 03 August 2015 – Ipsen announced that its partner, Lexicon Pharmaceuticals, Inc., disclosed positive results from the pivotal Phase 3 TELESTAR study. TELESTAR evaluated the efficacy and safety of telotristat etiprate for carcinoid syndrome patients with metastatic neuroendocrine tumor (NET) inadequately controlled by somatostatin analog (SSAs), the current standard of care.
- On 31 August 2015 – Ipsen announced that The Lancet Neurology has published online at <http://www.thelancet.com/neurology> the detailed results from the Ipsen sponsored phase III randomized study (NCT01313299) showing the efficacy and safety of Dysport® in post-stroke or traumatic brain injury patients with upper limb spasticity. This international phase III registration study led to the approval of Dysport® for the treatment of ULS in the US by the FDA on July 16, 2015. In Europe, the upper limb spasticity elements of the Dysport® SmPC have already been modified in some countries to include key medical data. Regulatory procedures are still ongoing in different European and Rest of World countries.
- On 29 September 2015 – Ipsen announced that its partner, Lexicon presented phase III TELESTAR study data at ECC 2015 (Vienna, Austria) showing that telotristat etiprate reduced the average number of daily bowel movements in patients with carcinoid syndrome not adequately controlled by somatostatin analogues.
- On 1 October 2015 – Ipsen announced that, in collaboration with the U.S. FDA (Food and Drug Administration), an additional batch of Increlex® will be available for commercial distribution starting in November, 2015.
- On 1 October 2015 – Ipsen announced the appointment of Stéphane Bessette as Executive Vice President, Human Resources of the Ipsen Group, as of today. He will report to Christel Bories, Deputy Chief Executive Officer of Ipsen, and will sit on the Executive Committee.
- On 28 October 2015 – Ipsen and Telesta Therapeutics Inc. announced that they have entered into an exclusive licensing agreement for Ipsen to develop and commercialize MCNA<sup>1</sup> for the treatment of high risk non-muscle invasive bladder cancer (NMIBC) in all countries of the world, with the exception of the

<sup>1</sup> *Mycobacterium phlei* cell wall-nucleic acid complex



United States, where Telesta is establishing commercial operations, Canada, South Africa, Mexico, South Korea and Japan. Under the financial terms of the agreement, Telesta is eligible to receive up to US\$137 million in upfront and milestone payments comprising a US\$10 million upfront payment and additional payments contingent upon achievement of regulatory and sales milestones. In addition, Telesta is eligible to receive meaningful tiered double-digit royalties on net sales of MCNA in the licensed territories.

## APPENDIX

### RISK FACTORS

The Group operates in an environment which is undergoing rapid change and exposes its operations to a number of risks, some of which are outside its control. The risks and uncertainties set out below are not exhaustive and the reader is advised to refer to the Group's 2014 Registration Document available on its website ([www.ipsen.com](http://www.ipsen.com)).

- The Group is faced with uncertainty in relation to the prices set for all its products, in so far as medication prices have come under severe pressure over the last few years as a result of various factors, including the tendency for governments and payers to reduce prices or reimbursement rates for certain drugs marketed by the Group in the countries in which it operates, or even to remove those drugs from lists of reimbursable drugs.
- The Group depends on third parties to develop and market some of its products, which generates or may generate substantial royalties for the Group, but these third parties could behave in ways that cause damage to the Group's business. 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.
- Actual results may depart significantly from the objectives given that a new product can appear to be promising at a development stage, or after clinical trials, but never be launched on the market, or be launched on the market but fail to sell, notably for regulatory or competitive reasons.
- The Research and Development process typically lasts between eight and twelve years from the date of discovery to a product being brought to market. This process involves several stages; at each stage, there is a substantial risk that the Group could fail to achieve its objectives and be forced to abandon its efforts in respect of products in which it has invested significant amounts. Thus, in order to develop viable products from a commercial point of view, the Group must demonstrate, by means of pre-clinical and clinical trials, that the molecules in question are effective and are not harmful to humans. The Group cannot be certain that favorable results obtained during pre-clinical trials will subsequently be confirmed during clinical trials, or that the results of clinical trials will be sufficient to demonstrate the safety and efficacy of the product in question such that the required marketing approvals can be obtained.
- The Group must deal with or may have to deal with competition (i) from generic products, particularly in relation to Group products which are not protected by patents, such as Forlax<sup>®</sup> and Smecta<sup>®</sup> (ii), products which, although they are not strictly identical to the Group's products or which have not demonstrated their bioequivalence, may obtain a marketing authorization for indications similar to those of the Group's products pursuant to the bibliographic reference regulatory procedure (well established medicinal use) before the patents protecting its products expire. Such a situation could result in the Group losing market share which could affect its current level of growth in sales or profitability.
- Third parties might claim the benefit of intellectual property rights with respect to the Group's inventions. The Group provides the third parties with which it collaborates (including universities and other public or private entities) with information and data in various forms relating to the research, development, manufacturing and marketing of its products. Despite the precautions taken by the Group with regard to these entities, in particular of a contractual nature, they (or certain of their members or affiliates) could claim ownership of intellectual property rights arising from the trials carried out by their employees or any other intellectual property right relating to the Group's products or molecules in development.
- The Group's strategy includes acquiring companies or assets which may enable or facilitate access to new markets, research projects or geographical regions or enable the Group to realize synergies with its existing businesses. Should the growth prospects or earnings potential of such assets as well as valuation assumptions change materially from initial assumptions, the Group might be under the obligation to adjust the values of these assets in its balance sheet, thereby negatively impacting its results and financial situation.
- The marketing of certain products by the Group has been and could be affected by supply shortages and other disruptions. Such difficulties may be of both a regulatory nature (the need to correct certain

technical problems in order to bring production sites into compliance with applicable regulations) and a technical nature (difficulties in obtaining supplies of satisfactory quality or difficulties in manufacturing active ingredients or drugs complying with their technical specifications on a sufficiently reliable and uniform basis). This situation may result in inventory shortages and/or in a significant reduction in the sales of one or more products. More specifically, in their US Hopkinton facility, Lonza, our supplier of IGF-1 (Increlex<sup>®</sup> drug substance), is experiencing manufacturing issues with Increlex<sup>®</sup>. Supply interruption occurred in mid-June 2013 in the US and in Q3 2013 in Europe and the rest of the world. On December 18<sup>th</sup> 2013, Ipsen announced that Lonza had successfully re-manufactured the active ingredient of Increlex<sup>®</sup> and that the European Medicines Agency (EMA) had been informed that Ipsen was preparing for the resupply of Increlex<sup>®</sup> in the European Union. Consultations with the National competent authorities have allowed a resupply in Europe early 2014. In the United States, Ipsen has released one batch of Increlex<sup>®</sup>'s active ingredient on 2 June 2014 and a second one in September 2014. An additional batch of Increlex<sup>®</sup> will be available for commercial distribution starting in November 2015. Ipsen continues to work closely with the FDA to make additional Increlex<sup>®</sup> lots available as soon as possible.

- In certain countries exposed to significant public deficits, and where the Group sells its drugs directly to public hospitals, the Group could face discount or lengthened payment terms or difficulties in recovering its receivables in full. The Group closely monitors the evolution of the situation in Southern Europe where hospital payment terms are especially long. More generally, the Group may also be unable to purchase sufficient credit insurance to protect itself adequately against the risk of payment default from certain customers worldwide. Such situations could negatively impact the Group's activities, financial situation and results.
- In the normal course of business, the Group is or may be involved in legal or administrative proceedings. Financial claims are or may be brought against the Group in connection with some of these proceedings.
- The cash pooling arrangements for foreign subsidiaries outside the euro zone expose the Group to financial foreign exchange risk. The variation of these exchange rates may impact significantly the Group's results.