

## Ipsen reports 12.2%<sup>1</sup> sales growth for the third quarter of 2016 and raises full year guidance

- Acceleration of Group sales growth at 12.2%<sup>1</sup> in the third quarter resulting in 10.5%<sup>1</sup> sales growth for the first 9 months driven by Specialty Care
  - Guidance 2016 raised

Paris (France), October 26, 2016 - Ipsen (Euronext: IPN; ADR: IPSEY), a global specialty-driven pharmaceutical group, today reported its sales for the third quarter and first nine months of 2016.

### Third quarter and first nine months 2016 unaudited IFRS consolidated sales

(in million euros)	Third Quarter				Nine Months			
	2016	2015	% Variation	% Variation at constant currency	2016	2015	% Variation	% Variation at constant currency
<b>Specialty Care</b>	<b>319.7</b>	<b>275.6</b>	<b>16.0%</b>	<b>17.8%</b>	<b>933.2</b>	<b>824.5</b>	<b>13.2%</b>	<b>15.5%</b>
of which Somatuline®	137.0	103.4	32.5%	34.1%	391.9	291.6	34.4%	36.0%
of which Decapeptyl®	84.2	81.6	3.2%	6.3%	251.8	250.8	0.4%	2.8%
of which Dysport®	73.9	68.2	8.3%	9.3%	213.5	208.8	2.3%	5.9%
<b>Primary Care</b>	<b>70.9</b>	<b>78.9</b>	<b>-10.1%</b>	<b>-7.5%</b>	<b>221.2</b>	<b>243.8</b>	<b>-9.3%</b>	<b>-6.4%</b>
of which Smecta®	25.3	26.7	-5.3%	-1.0%	79.4	89.1	-10.8%	-6.7%
of which Forlax®	9.0	10.0	-9.9%	-8.8%	29.1	28.8	1.1%	2.5%
of which Tanakan®	8.9	12.8	-30.6%	-31.0%	27.7	37.0	-25.0%	-23.2%
<b>Group sales</b>	<b>390.6</b>	<b>354.4</b>	<b>10.2%</b>	<b>12.2%</b>	<b>1 154.4</b>	<b>1 068.3</b>	<b>8.1%</b>	<b>10.5%</b>

Commenting on the third quarter 2016 performance, **David Meek, Chief Executive Officer of Ipsen** said: *“We are satisfied with the excellent performance achieved in the third quarter. The momentum of the Specialty Care business accelerated in the third quarter, led by the strong global performance of Somatuline® as well as a strong performance of Dysport® in the US and Decapeptyl® in Europe. The Primary Care business is still experiencing challenges in emerging markets and in the third quarter was particularly adversely impacted by a difficult market environment in Russia and Algeria and a slower ramp-up of the new commercial strategy in China.”*

**David Meek** added: *“We advanced several pipeline programs during the quarter, most notably for our oncology portfolio the Cabometyx® program. The recent approval for the second line treatment of advanced Renal Cell Carcinoma (RCC) in Europe and positive clinical results from the CABOSUN study in first line advanced RCC reinforce our conviction in the potential of Cabometyx®. We are fully committed to the launch of Cabometyx® in the first European countries in the coming weeks.”*

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

### **Third quarter 2016 sales highlights**

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

**Consolidated Group sales** grew 12.2% to €390.6 million.

Sales of **Specialty Care** products reached €319.7 million, up 17.8% year-on-year. The relative weight of Specialty Care continued to increase to reach 81.8% of Group sales, compared to 77.8% the previous year.

**Somatuline**<sup>®</sup> sales reached €137.0 million, up 34.1%, year-on-year, driven by the continued strong growth in the United States, and by a good overall performance in Europe, notably in Germany, France, and the UK.

**Decapeptyl**<sup>®</sup> sales reached €84.2 million, up 6.3% year-on-year, supported by strong volume growth in Europe.

**Dysport**<sup>®</sup> sales reached €73.9 million, up 9.3% year-on-year, led by a solid performance in the United States, notably in aesthetics through the Galderma partnership. This good performance was negatively impacted by volume declines in Brazil due to importation issues and in Russia due to lower demand.

**Primary Care** product sales totaled €70.9 million, down 7.5% year-on-year, affected by the decline in sales of Tanakan<sup>®</sup> in Russia, Forlax<sup>®</sup> in Algeria, and also the tail portfolio in France.

**Smecta**<sup>®</sup> sales reached €25.3 million, down 1.0% year-on-year, affected by the sales decrease in China with a slower ramp-up of the new commercial strategy in China, as well as in France and in Italy despite good performance in Russia.

**Forlax**<sup>®</sup> sales amounted to €9.0 million, down 8.8% year-on-year, affected by the sales decline in Algeria where import programs have been suspended and despite good volume growth in France.

**Tanakan**<sup>®</sup> sales comprised €8.9 million, down 31.0% year-on-year, impacted by continued market challenges in Russia.

### **2016 objectives revised**

Based on the performance of the first nine months of 2016, the Group raises its guidance for **Specialty Care sales to greater or equal to 15% growth** and revises its guidance for **Primary Care sales to a range of -3% to -5%**. The guidance for **Core Operating margin is raised to around 22%**.

	<i>Previous FY 2016 guidance</i>	<i>Revised FY 2016 guidance</i>
Specialty Care sales	Growth >+12%	Growth ≥+15%
Primary Care sales	Slight growth	-3% to -5%
Core Operating margin <sup>1</sup>	Around 21%	Around 22%

Sales objectives are set at constant currency.

<sup>1</sup> As percentage of net sales

## About Ipsen

Ipsen is a global specialty-driven pharmaceutical group with total sales exceeding €1.4 billion in 2015. Ipsen sells more than 20 drugs in more than 115 countries, with a direct commercial presence in more than 30 countries. Ipsen's ambition is to become a leader in specialty healthcare solutions for targeted debilitating diseases. Its fields of expertise cover oncology, neurosciences and endocrinology (adult & pediatric). Ipsen's commitment to oncology is exemplified through its growing portfolio of key therapies improving the care of patients suffering from neuro-endocrine tumors, prostate cancer, bladder cancer and renal cancer. 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/Paris-Saclay, France; Slough/Oxford, UK; Cambridge, US). In 2015, R&D expenditures neared €193 million. The Group has more than 4,600 employees worldwide. Ipsen's shares are traded on segment A of Euronext Paris (stock code: IPN, ISIN code: FR0010259150) and are 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 trades 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 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 2015 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 2016 and 2015:

### Sales by therapeutic area and by product<sup>1</sup>

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 quarter and the first nine months of 2016 and 2015:

(in million euros)	Third Quarter				Nine Months			
	2016	2015	% Variation	% Variation at constant currency	2016	2015	% Variation	% Variation at constant currency
<b>Oncology</b>	<b>225.6</b>	<b>189.1</b>	<b>19.3%</b>	<b>21.5%</b>	<b>657.5</b>	<b>555.4</b>	<b>18.4%</b>	<b>20.3%</b>
Somatuline <sup>®</sup>	137.0	103.4	32.5%	34.1%	391.9	291.6	34.4%	36.0%
Decapeptyl <sup>®</sup>	84.2	81.6	3.2%	6.3%	251.8	250.8	0.4%	2.8%
Hexvix <sup>®</sup>	4.4	4.1	6.2%	6.7%	13.8	12.9	6.9%	7.2%
<b>Neurosciences</b>	<b>74.2</b>	<b>68.5</b>	<b>8.4%</b>	<b>9.4%</b>	<b>214.7</b>	<b>209.6</b>	<b>2.5%</b>	<b>6.2%</b>
Dysport <sup>®</sup>	73.9	68.2	8.3%	9.3%	213.5	208.8	2.3%	5.9%
<b>Endocrinology</b>	<b>19.8</b>	<b>18.0</b>	<b>10.3%</b>	<b>11.4%</b>	<b>60.9</b>	<b>59.6</b>	<b>2.3%</b>	<b>3.1%</b>
NutropinAq <sup>®</sup>	13.3	13.9	-3.8%	-2.8%	43.7	45.5	-4.0%	-3.4%
Increlex <sup>®</sup>	6.5	4.1	57.5%	58.8%	17.2	14.0	23.1%	23.9%
<b>Specialty Care</b>	<b>319.7</b>	<b>275.6</b>	<b>16.0%</b>	<b>17.8%</b>	<b>933.2</b>	<b>824.5</b>	<b>13.2%</b>	<b>15.5%</b>
<b>Gastroenterology</b>	<b>52.0</b>	<b>53.6</b>	<b>-3.1%</b>	<b>0.8%</b>	<b>155.3</b>	<b>167.4</b>	<b>-7.2%</b>	<b>-3.5%</b>
Smecta <sup>®</sup>	25.3	26.7	-5.3%	-1.0%	79.4	89.1	-10.8%	-6.7%
Forlax <sup>®</sup>	9.0	10.0	-9.9%	-8.8%	29.1	28.8	1.1%	2.5%
<b>Cognitive Disorders</b>	<b>8.9</b>	<b>12.8</b>	<b>-30.6%</b>	<b>-31.0%</b>	<b>27.7</b>	<b>37.0</b>	<b>-25.0%</b>	<b>-23.2%</b>
Tanakan <sup>®</sup>	8.9	12.8	-30.6%	-31.0%	27.7	37.0	-25.0%	-23.2%
<b>Other Primary Care</b>	<b>4.7</b>	<b>6.3</b>	<b>-25.3%</b>	<b>-25.1%</b>	<b>18.1</b>	<b>21.2</b>	<b>-14.5%</b>	<b>-14.3%</b>
<b>Drug-related Sales</b>	<b>5.3</b>	<b>6.2</b>	<b>-13.4%</b>	<b>-13.4%</b>	<b>20.1</b>	<b>18.3</b>	<b>9.6%</b>	<b>9.6%</b>
<b>Primary Care</b>	<b>70.9</b>	<b>78.9</b>	<b>-10.1%</b>	<b>-7.5%</b>	<b>221.2</b>	<b>243.8</b>	<b>-9.3%</b>	<b>-6.4%</b>
<b>Group Sales</b>	<b>390.6</b>	<b>354.5</b>	<b>10.2%</b>	<b>12.2%</b>	<b>1 154.4</b>	<b>1 068.3</b>	<b>8.1%</b>	<b>10.5%</b>

In the third quarter of 2016, sales reached €390.6 million, up 12.2%, led by the 17.8% growth of Specialty Care sales, while Primary Care sales declined by 7.5%. In the first nine months of 2016, sales amounted to €1,154.4 million, up 10.5%, driven by the 15.5% growth of Specialty Care sales, while Primary Care sales declined by 6.4%.

In the third quarter of 2016, sales of **Specialty Care** products amounted to €319.7 million, up 17.8% year-on-year. In the first nine months of 2016, sales totaled €933.2 million, up 15.5%. Oncology sales grew by 20.3%, Neurosciences sales grew by 6.2%, and Endocrinology sales by 3.1%. Over the period, the relative weight of Specialty Care continued its increase to reach 80.8% of Group sales, compared to 77.2% in the previous year.

In **Oncology**, sales reached €225.6 million in the third quarter of 2016, up 21.5% year-on-year, driven by the continued acceleration of Somatuline<sup>®</sup> growth in the United States and in Europe. In the first nine

<sup>1</sup> New sales reporting according to main therapeutic indication of each project

months of 2016, sales amounted to €657.5 million, up 20.3%. Over the period, Oncology sales represented 57.0% of total Group sales, compared to 52.0% in the previous year.

**Somatuline**<sup>®</sup> – In the third quarter of 2016, sales reached €137.0 million, up 34.1%. In the first nine months of 2016, sales amounted to €391.9 million, up 36.0%. Somatuline<sup>®</sup>'s improved performance was driven by strong volume growth and a continued favorable pricing trend in North America and by a strong performance in most European countries, notably in Germany, Poland, and France.

**Decapeptyl**<sup>®</sup> – In the third quarter of 2016, sales totaled €84.2 million, up 6.3% year-on-year, led by strong volume growth in Europe. In the first nine months of 2016, sales amounted to €251.8 million, up 2.8%. Decapeptyl<sup>®</sup>'s growth was negatively impacted by competition and price pressure in China as well as difficulties importing the drug in some Middle East countries.

**Hexvix**<sup>®</sup> – In the third quarter of 2016, sales amounted to €4.4 million, up 6.7% year-on-year. In the first nine months of 2016, sales of Hexvix<sup>®</sup> reached €13.8 million, up 7.2%, mainly driven by the good performance in Germany, which accounts for the majority of product sales.

In **Neurosciences**, sales of **Dysport**<sup>®</sup> reached €73.9 million in the third quarter of 2016, up 9.3% year-on-year, driven by the product strong volume growth in the US aesthetics market. In the first nine months of 2016, sales amounted to €213.5 million, up 5.9%. This was driven by good performances in Russia and Germany and by the aesthetics business in the US with partner Galderma, despite the negative impact of inventory patterns at the beginning of the year and importation issues in the third quarter in Brazil, and difficulties with a partner in Asia. Over the period, Neurosciences sales represented 18.6% of total Group sales, compared to 19.6% for the previous year.

In **Endocrinology**, sales of **NutropinAq**<sup>®</sup> reached €13.3 million in the third quarter of 2016, down 2.8% year-on-year. In the first nine months of 2016, sales amounted to €43.7 million, down 3.4%, impacted by lower volumes, especially in Germany and the UK, and partly offset by a good performance in France. In the third quarter of 2016, sales of **Increlex**<sup>®</sup> reached €6.5 million, up 58.8% year-on-year, mostly driven by the United States. In the first nine months of 2016, sales amounted to €17.2 million, up 23.9%. Over the period, Endocrinology sales represented 5.3% of total Group sales, compared to 5.6% in the previous year.

In the third quarter of 2016, **Primary Care** sales totaled €70.9 million, down 7.5% year-on-year, negatively impacted by **Tanakan**<sup>®</sup> and sales of other Primary Care products. In the first nine months of 2016, sales amounted to €221.2 million, down 6.4%, mainly impacted by **Tanakan**<sup>®</sup> sales in Russia and lower **Smecta**<sup>®</sup> sales in Asia. Over the period, Primary Care sales represented 19.2% of total Group sales, compared to 22.8% in the previous year.

In the third quarter of 2016, **Gastroenterology** sales reached €52.0 million, up 0.8% year-on-year led by **Etiasa**<sup>®</sup> and **Fortrans**<sup>®</sup>. In the nine months of 2016, sales amounted to €155.3 million, down 3.5%, negatively impacted by inventory trends in Asia for **Smecta**<sup>®</sup> as well as for **Fortrans**<sup>®</sup> in Europe and Asia following the product shortage at the beginning of the year and the delisting of **Bedelix**<sup>®</sup> in Algeria.

**Smecta**<sup>®</sup> – In the third quarter of 2016, sales reached €25.3 million, slightly down 1.0% year-on-year. The volume growth in Russia was offset by the sales decline in other countries including Ukraine and China. In the first nine months of 2016, sales amounted to €79.4 million, down 6.7%, affected by high inventories in China in the first nine months of 2015 and a slow ramp-up of the new commercial model, as well as inventory build in Vietnam last year for license product renewal, offsetting the good performance in Russia.

**Forlax**<sup>®</sup> – In the third quarter of 2016, sales reached €9.0 million, down 8.8% year-on-year. The good performance in France was offset by the sales decline in Algeria where imports have been suspended. In the first nine months of 2016, sales amounted to €29.1 million, up 2.5%, supported by growing sales to partners marketing the generic version of the product and a good performance in Italy.



In the **Cognitive Disorders** area, sales of **Tanakan**<sup>®</sup> reached €8.9 million in the third quarter of 2016, down 31.0% year-on-year, due continued market challenges in Russia. Sales in the first nine month of 2016 amounted to €27.7 million, down 23.2%.

Sales of **Other Primary Care** products reached €4.7 million in the third quarter of 2016, down 25.1% year-on-year. In the first nine months of 2016, sales amounted to €18.1 million, down 14.3%, mainly affected by the 20.4% decline of **Nisis**<sup>®</sup>/**Nisisco**<sup>®</sup> impacted by an additional 40.0% price cut in February 2015 in France, and by the underperformance of **Adrovanse**<sup>®</sup>, which is down 15.9% over the period.

In the third quarter of 2016, **Drug-related Sales (active ingredients and raw materials)** reached €5.3 million, down 13.4% year-on-year, mostly affected by import difficulties in Algeria. In the first nine months of 2016, sales amounted to €20.1 million, up 9.6% driven by solid sales to the Group partner Schwabe.

## Sales by geographical area

Group sales by geographical area in the third quarter and first nine months of 2016 and 2015:

(in million euros)	Third Quarter				Nine months			
	2016	2015	% Variation	% Variation at constant currency	2016	2015	% Variation	% Variation at constant currency
France	52.5	51.6	1.7%	1.7%	164.0	158.5	3.5%	3.5%
Germany	30.8	26.9	14.3%	14.3%	91.6	80.4	13.9%	13.9%
Italy	19.4	18.0	7.8%	7.8%	62.4	60.0	4.0%	4.0%
United Kingdom	17.5	19.4	-10.0%	7.6%	54.6	56.5	-3.4%	6.6%
Spain	15.8	15.5	1.9%	1.9%	50.7	48.1	5.4%	5.4%
<b>Major Western European countries</b>	<b>136.0</b>	<b>131.5</b>	<b>3.4%</b>	<b>6.0%</b>	<b>423.3</b>	<b>403.5</b>	<b>4.9%</b>	<b>6.3%</b>
Eastern Europe	40.4	40.3	0.2%	3.3%	125.6	124.4	0.9%	7.9%
Others Europe	41.8	39.6	5.5%	5.4%	125.9	116.2	8.4%	8.7%
<b>Other European Countries</b>	<b>82.2</b>	<b>79.9</b>	<b>2.8%</b>	<b>4.4%</b>	<b>251.5</b>	<b>240.6</b>	<b>4.5%</b>	<b>8.3%</b>
<b>North America</b>	<b>71.6</b>	<b>41.8</b>	<b>71.3%</b>	<b>72.0%</b>	<b>189.7</b>	<b>109.2</b>	<b>73.7%</b>	<b>73.9%</b>
Asia	54.6	54.7	-0.2%	3.9%	156.0	171.5	-9.1%	-5.7%
Other countries in the Rest of the world	46.2	46.5	-0.7%	-0.6%	134.0	143.4	-6.6%	-3.2%
<b>Rest of the World</b>	<b>100.8</b>	<b>101.3</b>	<b>-0.4%</b>	<b>1.8%</b>	<b>289.9</b>	<b>315.0</b>	<b>-7.9%</b>	<b>-4.5%</b>
<b>Group Sales</b>	<b>390.6</b>	<b>354.5</b>	<b>10.2%</b>	<b>12.2%</b>	<b>1 154.4</b>	<b>1 068.3</b>	<b>8.1%</b>	<b>10.5%</b>

In the third quarter of 2016, sales in the **Major Western European countries** reached €136.0 million, up 6.0% year-on-year. In the first nine months of 2016, sales in the Major Western European countries amounted to €423.3 million, up 6.3%. Over the period, sales in the Major Western European countries represented 36.7% of total Group sales, compared to 37.8% in the previous year.

**France** – In the third quarter of 2016, sales reached €52.5 million, up 1.7% year-on-year. In the first nine months of 2016, sales amounted to €164.0 million, up 3.5%, driven by the sustained growth of Somatuline<sup>®</sup>, Decapeptyl<sup>®</sup>, and NutropinAq<sup>®</sup>. Primary Care sales continued to decrease, notably due to Tanakan<sup>®</sup>, Adrovanse<sup>®</sup>, and Nisis<sup>®</sup>/Nisisco<sup>®</sup>, but the decline was partly offset by the good performance of Forlax<sup>®</sup> and Smecta<sup>®</sup>. The relative weight of France in the Group's consolidated sales has continued to decrease to represent 14.2% of total Group sales, compared to 14.8% in the previous year.

**Germany** – In the third quarter of 2016, sales reached €30.8 million, up 14.3% year-on-year. In the first nine months of 2016, sales amounted to €91.6 million, up 13.9%, driven by strong growth of Somatuline<sup>®</sup> and Dysport<sup>®</sup> as well as supply sales to the Group partner Schwabe. Over the period, sales in Germany represented 7.9% of total Group sales, compared to 7.5% in the previous year.

**Italy** – In the third quarter of 2016, sales reached €19.4 million, up 7.8% year-on-year. In the first nine months of 2016, sales amounted to €62.4 million, up 4.0%. The strong growth of Somatuline<sup>®</sup> and Forlax<sup>®</sup> was partly offset by the sales decline of Dysport<sup>®</sup>. Over the period, sales in Italy represented 5.4% of total Group sales, compared to 5.6% in the previous year.

**United Kingdom** – In the third quarter of 2016, sales reached €17.5 million, up 7.6% year-on-year. In the first nine months of 2016, sales amounted to €54.6 million, up 6.6%, driven by Somatuline<sup>®</sup> and Decapeptyl<sup>®</sup> and a positive impact from the 2016 price adjustment mechanism (PPRS<sup>1</sup>). Over the period, the United Kingdom represented 4.7% of total Group sales, compared to 5.3% in the previous year.

<sup>1</sup> Pharmaceutical Price Regulation Scheme



**Spain** – In the third quarter of 2016, sales reached €15.8 million, up 1.9% year-on-year. In the first nine months of 2016, sales amounted to €50.7 million, up 5.4%, affected by a price decrease on Somatuline<sup>®</sup> offset by strong volume growth for the product, as well as for Decapeptyl<sup>®</sup>. Over the period, sales in Spain represented 4.4% of total Group sales, stable year-on-year.

In the third quarter of 2016, sales in **Other European countries** reached €82.2 million, up 4.4% year-on-year. In the first nine months of 2016, sales amounted to €251.5 million, up 8.3%, supported by the strong performance of Somatuline<sup>®</sup> across the region as well as Dysport<sup>®</sup> and Decapeptyl<sup>®</sup>, particularly in Russia and Ukraine, partly offset by the Tanakan<sup>®</sup> slowdown in Russia. Over the period, sales in the region represented 21.8% of total Group sales compared to 22.5% in the previous year.

In the third quarter of 2016, sales generated in **North America** reached €71.6 million, up 72.0% year-on-year. In the first nine months of 2016, sales amounted to €189.7 million, up 73.9%, supported by the acceleration of Somatuline<sup>®</sup> growth following the launch of the neuroendocrine tumor indication and the growth of Dysport<sup>®</sup> particularly driven by strong growth in aesthetics through the Galderma partnership. Over the period, sales in North America represented 16.4% of total Group sales, compared to 10.2% in the previous year.

In the third quarter of 2016, sales in the **Rest of the World** reached €100.8 million, up 1.8% year-on-year mainly driven by the performance of Somatuline<sup>®</sup> in Japan and Brazil. In the first nine months of 2016, sales amounted to €289.9 million, down 4.5%. Sales were impacted by unfavorable inventory effects on Smecta<sup>®</sup> in China, the delisting of Bedelix<sup>®</sup> in Algeria, and difficulties importing Decapeptyl<sup>®</sup> in the Middle East. Furthermore, adverse inventory trends in Brazil and difficulties with a partner in Asia negatively impacted Dysport<sup>®</sup>. Over the period, sales in the Rest of the World represented 25.1% of total Group sales, compared to 29.5% in the previous year.

## MAJOR DEVELOPMENTS

During the first nine months 2016, major developments included:

- January 6, 2016 – Ipsen and Galderma announced that they have expanded the geographical scope of their neurotoxin partnership, whereby Galderma has acquired the exclusive rights to develop, promote, and distribute Dysport® in the aesthetic indications in the APAC countries (China, India, South Korea, and Indonesia under certain conditions).
- January 26, 2016 – Ipsen announced that the scientific journal *Pediatrics* published the detailed results of the Phase 3 randomized study (NCT01249417) that showed both the efficacy and the safety of Dysport® in the treatment of dynamic equinus foot deformity (also known as pediatric lower limb spasticity), a condition associated with cerebral palsy in children.
- February 16, 2016 – Ipsen announced at its meeting on February 15<sup>th</sup>, 2016, that the Board of Directors decided to change the Company's form of governance by separating the duties of Chairman of the Board of Directors and Chief Executive Officer. The Board of Directors confirmed that Mr. Marc de Garidel shall fulfill the duties of Chairman of the Board of Directors within the framework of the new governance structure and recorded the departure of Mrs. Christel Bories as Deputy Chief Executive Officer.
- March 1, 2016 – Exelixis and Ipsen jointly announced an exclusive licensing agreement for the commercialization and further development of cabozantinib, which is Exelixis' lead oncology drug. Under the agreement, Ipsen will have exclusive commercialization rights for current and potential future cabozantinib indications outside the United States, Canada and Japan, including COMETRIQ®, which is currently approved in the European Union (EU) for the treatment of adult patients with progressive, unresectable, locally advanced or metastatic medullary thyroid cancer (MTC).
- April 25, 2016 – Ipsen announced that its partner Exelixis received approval from the U.S. Food and Drug Administration (FDA) for CABOMETRYX™ (cabozantinib) tablets for the treatment of patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy.
- April 26, 2016 – Ipsen and Probi jointly announced the signature of a license and supply agreement for the commercialization of Probi's probiotic strain *Lactobacillus plantarum* 299v (LP299V®). The agreement covers 18 countries, primarily within EU and emerging markets.
- May 23, 2016 – Ipsen announced that its partner Exelixis reported positive top-line results from the CABOSUN randomized Phase 2 trial of cabozantinib in patients with previously untreated advanced renal cell carcinoma (RCC). The trial met its primary endpoint through demonstrating a statistically significant and clinically meaningful improvement in progression-free survival (PFS) for cabozantinib compared with sunitinib in patients with advanced intermediate- or poor-risk RCC.
- May, 31 2016 – Ipsen's partner, Lexicon, announced FDA Priority Review of new drug application for telotristat etiprate for the treatment of carcinoid syndrome.
- June 5, 2016 – Exelixis and Ipsen reported the overall survival (OS) results from the Phase 3 METEOR trial of CABOMETRYX™ (cabozantinib) tablets in patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy. The OS results demonstrate that CABOMETRYX™ reduces the risk of death by one third versus everolimus.
- June 6, 2016 – Exelixis and Ipsen announced the presentation of positive data from subgroup analyses of the pivotal METEOR trial comparing CABOMETRYX™ (cabozantinib) tablets with everolimus in 658 patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy.

- June 6, 2016 – Ipsen announced the launch of an employee shareholding plan. This plan aims to align employees with the Group’s development and performance. The main terms and conditions of this plan are described hereafter.
- June 9, 2016 – Ipsen announced the successful issuance of its inaugural, unsecured 7-year Notes for a total of €300 million. These Notes mature on June 16, 2023, and pay interest at an annual rate of 1.875%.
- July 11, 2016 – The Board of Directors of Ipsen met on July 8, 2016, and appointed David Meek as Chief Executive Officer, effective July 18, 2016. On this date, Marc de Garidel assumed the role of non-executive chairman. Marc de Garidel continues to serve the Board of Directors through his deep industry expertise.
- July 18, 2016 – Ipsen issued a statement about the acceptance by the European Medicines Agency (EMA) of the marketing authorization application for telotristat etiprate to treat carcinoid syndrome caused by neuroendocrine tumors, in combination with somatostatin analogues.
- July 22, 2016 – Exelixis and Ipsen announced that the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the EMA provided a positive opinion for Cabometyx™ (cabozantinib) 20, 40, 60mg for the treatment of advanced renal cell carcinoma (RCC) in adults following prior vascular endothelial growth factor (VEGF)-targeted therapy and recommended it for marketing authorization.
- August 01, 2016 – Ipsen reported that the U.S. Food and Drug Administration (FDA) approved Dysport® (abobotulinumtoxinA) for injection for the treatment of pediatric lower limb (PLL) spasticity in children two years of age and older.
- September 14, 2016 – Ipsen disclosed that the European Commission approved Cabometyx™ (cabozantinib) 20, 40, 60 mg tablets for the treatment of advanced renal cell carcinoma (RCC) in adults following prior vascular endothelial growth factor (VEGF)-targeted therapy.
- October 7, 2016 – Ipsen announced that its partner Exelixis released Phase 1 trial results for cabozantinib in combination with nivolumab in advanced genitourinary tumors.
- October 10, 2016 – Ipsen and its partner Exelixis announced detailed results from the CABOSUN randomized phase 2 trial comparing cabozantinib versus sunitinib in patients with previously untreated advanced renal cell carcinoma (RCC) with intermediate- or poor-risk disease per the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC).

## 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 2015 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 (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.
- 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.