

**Ipsen: sales in the fourth quarter and full year 2014**

**Ipsen reports a solid 5.7%<sup>1</sup> growth in 2014, driven by specialty care and at the top end of the guidance range**

- **Specialty care sales up 9.9%<sup>1</sup> in 2014**
  - Somatuline<sup>®</sup> up 16.8%<sup>1</sup>, with strong growth in the US and Europe
  - Dysport<sup>®</sup> up 8.6%<sup>1</sup>, driven by strong performance in aesthetic medicine
  - Decapeptyl<sup>®</sup> up 6.5%<sup>1</sup>, with growth resuming in China and the Middle East
- **Primary care sales up 0.5%<sup>1</sup> in 2014, driven by international growth**

Paris (France), 3 February 2015 - Ipsen (Euronext: IPN; ADR: IPSEY) today reported its sales for the fourth quarter and the full year 2014.

**Unaudited IFRS consolidated sales**

(in million euros)	4 <sup>th</sup> quarter				12 months			
	2014	2013	% Variation	% Variation at constant currency	2014	2013	% Variation	% Variation at constant currency
<b>SALES BY REGION</b>								
Major Western European countries	128.2	121.5	5.5%	4.7%	509.1	497.3	2.4%	1.8%
Other European countries	79.9	83.6	-4.4%	4.6%	324.1	329.4	-1.6%	3.6%
North America	21.2	14.2	49.4%	36.3%	79.2	64.2	23.2%	23.7%
Rest of the world	77.8	73.8	5.4%	0.4%	362.5	333.9	8.6%	10.4%
<b>Group Sales</b>	<b>307.1</b>	<b>293.0</b>	<b>4.8%</b>	<b>5.2%</b>	<b>1274.8</b>	<b>1 224.8</b>	<b>4.1%</b>	<b>5.7%</b>
<b>SALES BY THERAPEUTIC AREA</b>								
Specialty care	228.8	209.9	9.0%	8.5%	947.1	871.1	8.7%	9.9%
Primary care	74.2	77.5	-4.3%	-1.5%	311.9	320.2	-2.6%	0.5%
<b>Total Drug Sales</b>	<b>303.0</b>	<b>287.4</b>	<b>5.4%</b>	<b>5.9%</b>	<b>1259.0</b>	<b>1 191.3</b>	<b>5.7%</b>	<b>7.4%</b>
Drug-related sales*	4.1	5.6	-27.5%	-28.5%	15.9	33.5	-52.7%	-53.0%
<b>Group Sales</b>	<b>307.1</b>	<b>293.0</b>	<b>4.8%</b>	<b>5.2%</b>	<b>1274.8</b>	<b>1 224.8</b>	<b>4.1%</b>	<b>5.7%</b>

\* Active substances and raw materials. Drug-related sales are affected by an unfavorable effect arising from the change in methodology for the consolidation of sales of the Swiss company Linnea. Indeed, sales of active ingredients and raw materials made by Linnea, partner on which Ipsen and the Schwabe Group exercise joint control, will from now on be consolidated under the equity method of accounting

<sup>1</sup> Year-on-year growth excluding foreign exchange impacts (see appendix)

Commenting on the full year 2014 sales performance, **Marc de Garidel, Chairman and Chief Executive Officer of Ipsen**, said: *"In 2014, Specialty care sales grew 9.9%<sup>1</sup>, driven by the acceleration of Somatuline<sup>®</sup> growth across all geographies, Dysport<sup>®</sup> solid performance, and the rebound of Decapeptyl<sup>®</sup> after a particularly difficult year 2013. Moreover, Primary care started to level off thanks to its emerging markets presence."* **Marc de Garidel** added: *"2014 was marked by key milestones for the Group with the approval of Somatuline<sup>®</sup> in the United States for first line treatment of pancreatic and gastrointestinal neuroendocrine tumors (GEP-NET), the negotiation of an exclusive partnership with Galderma for the development and marketing of neurotoxins, and the materialization of our business development strategy with the acquisition of the European rights to telotristat etiprate. 2015 looks just as rich with the global launch of Somatuline<sup>®</sup> in GEP-NET, the potential US launch of Dysport<sup>®</sup> in spasticity and the tasquinimod phase III results in prostate cancer."*

### **Highlights of the fourth quarter and full year 2014 sales**

*Note: Unless stated otherwise, all variations in sales are stated excluding foreign exchange<sup>1</sup> impacts.*

**Group drug sales** grew 5.9% in the fourth quarter 2014 and 7.4% for the year. **Consolidated Group sales** grew 5.2% to €307.1 million in the fourth quarter 2014 and 5.7% to €1,274.8 million euros for the year.

Sales of **Specialty care** products reached €228.8 million in the fourth quarter 2014, up 8.5% year-on-year. In 2014, sales amounted to €947.1 million, up 9.9%. Sales in urology-oncology, endocrinology, and neurology grew by respectively 6.7%, 14.0% and 8.8%. In 2014, the relative weight of specialty care products continued to increase to reach 74.3% of total Group sales, compared to 71.1% the previous year.

Sales of **Decapeptyl<sup>®</sup>** reached €73.2 million in the fourth quarter 2014, down 4.2% year-on-year, and €316.6 million for the full year 2014, up 6.5%. Sales growth in 2014 benefited from a favorable comparison base due to weak product performance in the first nine months 2013 in China and in the Middle East, where Ipsen had limited the supply of its products due to the absence of payment guarantees, but was penalized in the fourth quarter 2014 by the strong pick-up in sales in these regions in the fourth quarter 2013. In 2014, Decapeptyl<sup>®</sup> performance nonetheless took place in a contracting pharmaceutical market in Europe, notably impacted by a more frequent use of co-payment in Southern Europe and a slowdown in the growth of Eastern European countries. As such, performance in France suffered from a decrease in volumes sold and from the implementation of a 4.0% price cut as of 1<sup>st</sup> April 2014.

Sales of **Somatuline<sup>®</sup>** reached €73.9 million in the fourth quarter 2014, up 20.6% year-on-year. In 2014, sales of Somatuline<sup>®</sup> grew 16.8% to €287.5 million, driven by strong volume and value growth in the United States, strong volume growth in Germany together with a reduction (from 16% to 7%) in mandatory rebates on prescription drug sales, and solid volume momentum in the United Kingdom. Somatuline<sup>®</sup> recorded good performance in Spain, France, the Netherlands, Denmark and Belgium, and was penalized by a price cut in Columbia.

Sales of **Dysport<sup>®</sup>** reached €59.2 million in the fourth quarter 2014, up 7.7% year-on-year. In 2014, Dysport<sup>®</sup> sales amounted to €254.5 million, up 8.6%, driven by the supply of the product to Galderma for aesthetic use and by the solid volume performance of the therapeutic and aesthetic segments in Brazil. Growth was affected by the intensification of competitive intensity in South Korea and United Kingdom, while benefiting in Germany from the reduction in mandatory rebates.

Sales of **Primary Care** products reached €74.2 million, down 1.5% year-on-year. In 2014, sales amounted to €311.9 million, up 0.5%. In France, sales of Primary care products declined 9.9%, affected by two 7.5% consecutive price cuts on Smecta<sup>®</sup> and the launch of a competing product to Tanakan<sup>®</sup> in March 2013. Internationally, sales increased 5.2%, driven by solid performance in China, Algeria and Russia, offsetting the decline in France. Primary care sales in France accounted for 27.8% of the Group's total primary care sales, compared to 30.1% the previous year.

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<sup>1</sup> See appendix

Sales of **Smecta**<sup>®</sup> reached €26.8 million in the fourth quarter 2014, down 7.3% year-on-year, mainly affected by the interruption of direct sales in Algeria, replaced from now on by the sales of the active principle to a local manufacturer, which are recorded in Drug-related sales. Restated for this item, sales increased 1.8% over the quarter. In 2014, sales amounted to €121.4 million euros, up 2.7%, driven by solid growth in Russia, Algeria and China, but affected in France by the two 7.5% price cuts implemented in January and July 2014 and a low level of gastroenteritis epidemic compared to last year.

Sales of **Tanakan**<sup>®</sup> reached €15.0 million euros in the fourth quarter 2014, down 9.7% year-on-year. In 2014, sales amounted to €62.6 million euros, down 0.6%, driven by the good performance of the product in Russia. The product's growth was penalized by the launch of a second "me-too" product in France in 2013 and by a change in the commercial model for Spain, where the product is now distributed by a partner.

Sales of **Forlax**<sup>®</sup> reached €10.1 million in the fourth quarter 2014, up 9.1% year-on-year. In 2014, sales amounted to €38.5 million euros, flat year-on-year, affected by the reinforcement of the "Tiers-Payant"<sup>1</sup> regulation in France and by the lower sales to our partners marketing generic versions of the product.

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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

## **About Ipsen**

Ipsen is a global specialty-driven pharmaceutical company with total sales exceeding €1.2 billion in 2014. 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. 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. In 2013, R&D expenditure totaled close to €260 million, representing more than 21% of Group sales. Moreover, Ipsen also has a significant presence in primary care. The Group has close to 4,600 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.

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## APPENDIX

### SALES EXCLUDING FOREIGN EXCHANGE IMPACTS

Unless stated otherwise, all variations in sales are stated excluding foreign exchange impacts by restating the Q4 and full year 2013 figures with the 2014 exchange rates.

### 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 2013 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), experienced manufacturing issues with Increlex<sup>®</sup> which led in 2013 to supply interruption in the US, Europe and the rest of the world. Consultations with the National competent authorities of the European Union have allowed a resupply in Europe early 2014. In the United States, Ipsen has released a first batch of Increlex<sup>®</sup>'s active ingredient on 2 June 2014 and a second one in September 2014. Ipsen anticipates that additional lots will be released in the coming months, as the company 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.

## MAJOR DEVELOPMENTS

During 2014, major developments included:

- On **10 January 2014** – Ipsen announced the appointment of Jonathan Barnsley as Executive Vice President in charge of Technical Operations. He is a member of the Executive Committee of the Ipsen group. He took up his new position on April 1<sup>st</sup>, 2014, reporting directly to Christel Bories, Deputy CEO of the Ipsen group.
- On **14 January 2014** – Ipsen and GW Pharmaceuticals plc announced that they have entered into an exclusive agreement for Ipsen to promote and distribute Sativex<sup>®</sup>, a sublingual cannabis extract spray intended for the treatment of spasticity due to multiple sclerosis in Latin America (excluding Mexico and the Islands of the Caribbean). GW will be responsible for commercial product supply to Ipsen. GW Pharmaceuticals and Ipsen aim to start regulatory filings in selected countries in Latin America during 2014 for the multiple sclerosis spasticity indication.
- On **14 January 2014** – Ipsen announced its decision to set up its own oncology team to commercialize Somatuline<sup>®</sup> Depot<sup>®</sup> (lanreotide) 120 mg Injection (« Somatuline<sup>®</sup> ») in neuroendocrine tumors in the US. Over the past few months, the Group had been considering both a “go-it-alone” and a partnership strategy following the communication of the data from the investigational CLARINET<sup>®</sup> phase III clinical study evaluating the antiproliferative effect of Somatuline<sup>®</sup> in the treatment of non-functioning gastrointestinal & pancreatic NETs (GEP NETs). Ipsen expects that these encouraging results will support a key long-term opportunity for the Group to access an US addressable market in excess of \$500 million<sup>1</sup>. Ipsen considers success in the US as a strategic priority. The “go-it-alone” option maximizes long term value creation and helps the US affiliate in reaching critical mass. Ipsen anticipates filing a Supplemental New Drug Application seeking an indication for Somatuline<sup>®</sup> in NETs in the first half of 2014. Maximum incremental annual cost associated with the launch of Somatuline<sup>®</sup> in the NET indication in the US is expected to range from €30 million to €40 million. As a result, US breakeven<sup>2</sup>, initially expected in 2014, is postponed to 2017. Ipsen will continue to implement cost containment initiatives to minimize impact on overall Group profitability.
- On **17 January 2014** – Ipsen announced at ASCO GI that ELECT<sup>®</sup> clinical trial of Somatuline<sup>®</sup> in the control of symptoms in GEP-NET patients with carcinoid syndrome met its primary endpoint. Results of the ELECT<sup>®</sup> phase III study (poster 268) showed that treatment with Somatuline<sup>®</sup> 120 mg versus placebo resulted in a statistically significant reduction in the number of days in which immediate release octreotide was used as rescue medication, representing a mean difference of -14.8% (95%CI: -26.8, -2.8; p = 0.017). Somatuline<sup>®</sup> significantly improved the rates of complete/partial treatment success versus placebo (odds ratio = 2.4; 95%CI: 1.1, 5.3; p = 0.036).
- On **22 January 2014** – Ipsen announced the implementation of new governance in the United States, following its recently announced decision to launch Somatuline<sup>®</sup> for oncology indications. Marc de Garidel will personally oversee this projected launch. Cynthia Schwalm will join Ipsen's US Operations to head up the Endocrinology/Oncology Business Unit as of 3 February, 2014. As of mid-August 2014, she will take over as General Manager of the US commercial affiliate.
- On **5 February 2014** – Ipsen announced the results of the international Phase III clinical trial of Dysport<sup>®</sup> Next Generation (DNG) in cervical dystonia and the results of the European Phase II clinical trial of DNG in glabellar lines. In the light of these results, Ipsen announces its intention to file the first ready-to-use liquid toxin A in Europe and in the Rest of the World<sup>3</sup> (ROW). DNG was clinically and statistically superior to placebo in the cervical dystonia Phase III study at the dose of 500 units at week 4 after single dose (adjusted mean reduction of 12.5 with DNG versus 3.9 with placebo as assessed by the Toronto Western Spasmodic Torticollis Rating Scale, or TWSTRS, total score). When compared to Dysport<sup>®</sup>, DNG did not demonstrate the statistical non-inferiority in efficacy at week 4 (adjusted mean reduction of 12.5 with DNG versus 14.0 with Dysport<sup>®</sup> in TWSTRS total score). This efficacy difference is unlikely to be of clinical relevance. After repeated dose, DNG showed comparable efficacy to that of Dysport<sup>®</sup> as observed in former Phase III studies<sup>4</sup>. DNG was clinically and statistically superior to placebo and comparable to Dysport<sup>®</sup> in the glabellar lines Phase II study at the dose of 50 units after

<sup>1</sup> Ipsen 2013 estimates of US NET market

<sup>2</sup> Commercial contribution excluding Increlex<sup>®</sup> (mecasermin [rDNA origin]) Injection sales and revenues from US collaboration with Galderma in aesthetic medicine

<sup>3</sup> Latin America, Middle East and Asia (excl. China and Japan)

<sup>4</sup> Truong D. et al. *Mov. Disord.*, 2005; 20 (7) 783-791; Truong et al., *Parkinsonism Relat Disord.* 2010 Jun;16(5):316-23

single dose. Across the studies, DNG showed safety profiles consistent with the known safety profile of Dysport®. Regarding DNG stability, analysis is still ongoing. The stability data trends are positive, providing confidence of achieving a commercially viable product. Ipsen is continuing stability testing to establish maximum shelf life across full product range. On the basis of these results and feedback from the Principal Investigator of the Phase III study, Ipsen intends to initiate a dialog with key agencies on the regulatory approach to file the first ready-to-use liquid toxin A in Europe and ROW<sup>1</sup>.

- On **7 February 2014** – Ipsen announced that the phase III clinical trial evaluating Decapeptyl® (triptorelin pamoate) 11.25 mg administered subcutaneously in patients with locally advanced or metastatic prostate cancer has met its primary endpoints. The full study results will be presented this year during a medical congress. Based on these results, Ipsen intends to apply for the addition of the subcutaneous route, alongside the intramuscular route, to the label of triptorelin pamoate 11.25 mg.
- On **18 March 2014** – Ipsen announced positive results from its phase IIa clinical trial assessing Dysport® in the treatment of Neurogenic Detrusor Overactivity (NDO) in patients with urinary incontinence not adequately managed by anticholinergics. Results show that treatment with Dysport® was associated with a mean reduction from baseline of urinary incontinence episodes greater than 75%, 12 weeks after the injection, regardless of how the drug is administered. These results were achieved with a single dose of Dysport® 750 Units injected in either 15 or 30 sites in the detrusor muscle. Efficacy was confirmed by improvement in urodynamic parameters and quality of life. The safety profile observed in the study is consistent with the safety profile expected in this indication.
- On **20 March 2014** – Ipsen announced that Mayroy, its controlling shareholder, had completed an institutional private placement of 5 888 290 shares representing c.7% of Ipsen's share capital, at a price of €29.50 per share. As part of this transaction, Ipsen purchased 842 542 of its own shares (representing 1% of its share capital) to be cancelled. Ipsen has been informed that the proceeds of this sale will be used to partially finance the repurchase by Mayroy of the entire stake held in its share capital by its minority shareholder, Opera Finance Europe, a Luxembourg-registered company controlled by Mrs Véronique Beaufour. Opera Finance Europe and its stakeholders do not sit on the Board of Directors of Ipsen and play no active role in the management of the Group. The repurchase of the balance of the stake of Opera Finance Europe will be financed by the delivery by Mayroy of Ipsen shares representing c.4% of Ipsen share capital. These shares will be placed into an escrow account for a period of 12 months following completion of the transaction.  
As a result of this transaction, Ipsen's free-float increases to c.40%<sup>2</sup> from c.30%. Mayroy's stake in Ipsen's share capital and voting rights now amounts to c.57.6%<sup>3</sup> and c.73.3%<sup>3</sup> respectively. The indirect stake held by Beech Tree (controlling shareholder of Mayroy) in Ipsen has slightly increased. Ipsen has also been informed that the shareholders' agreement between Beech Tree, its subsidiaries and the Schwabe family, which was entered into on December 31, 2008 in order to preserve the stability of Mayroy's controlling share ownership structure, has been renewed until 30 June 2015.
- On **9 April 2014** – 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). Ipsen was included by Euronext in the CAC® PME index.
- On **12 April 2014** – Ipsen announced that a first set of results on phase III clinical study of Dysport® in the treatment of adults suffering from Upper Limb Spasticity was presented on Saturday, April 12<sup>th</sup>, at the 8<sup>th</sup> World Congress for NeuroRehabilitation in Istanbul (Turkey). Four weeks after Dysport® injection, the Phase III clinical study results demonstrated that:
  - Patients treated with Dysport® showed a statistically significantly ( $p < 0.0001$ ) higher proportion of responders in muscle tone improvement versus placebo (i.e. exhibiting  $\geq 1$  point improvement as measured by the Modified Ashworth Scale, MAS). At week 4, patients treated with Dysport® 500 units and 1000 units showed responding rates of 73.8% and 78.5%, respectively, compared to 22.8% in the placebo arm;

<sup>1</sup> Latin America, Middle East and Asia (excl. China and Japan)

<sup>2</sup> Calculation taking into account the placement aforementioned, the cancellation of the Ipsen shares purchased as part of this transaction, and the cancellation of the 800 000 shares purchased as part of the program announced on 6 November 2013

- Patients treated with Dysport<sup>®</sup> showed a statistically significantly ( $p < 0.0001$ ) higher clinical benefit versus placebo, as measured by the Physician Global Assessment (PGA). At week 4, the mean PGA score for patients treated with Dysport<sup>®</sup> 500 units and 1000 units were 1.4 and 1.8, respectively, compared to 0.6 in the placebo arm.
- Additionally, patients treated with Dysport<sup>®</sup> showed a higher proportion of responders from baseline in improved passive function versus placebo (exhibiting  $\geq 1$  grade decrease as measured by the disability assessment scale). At week 4, patients treated with Dysport<sup>®</sup> 1000 units showed a statistically significant response rate of 62%. Patients treated with Dysport<sup>®</sup> 500 units showed a clinically relevant response rate of 50%. Placebo arm showed a 39% response rate.
- On **13 May 2014** – Ipsen announced that a supply of Increlex<sup>®</sup> will be available in the U.S. starting 2 June 2014. In collaboration with the FDA (Food and Drug Administration), Ipsen is releasing one batch of Increlex<sup>®</sup>'s active ingredient. Ipsen anticipates that additional lots will be released in the coming months, as the company continues to work closely with the FDA to make additional Increlex<sup>®</sup> lots available as soon as possible.
- On **1 July 2014** – Ipsen announced that it has submitted a Supplemental New Drug Application to the U.S. Food and Drug Administration (FDA) for Somatuline<sup>®</sup> Depot<sup>®</sup> 120mg injection for the treatment of gastroenteropancreatic neuroendocrine tumors (GEP-NETs). In the European Union, Ipsen has submitted national marketing authorization variations for Somatuline<sup>®</sup> Autogel<sup>®</sup> 120mg injection to the drug regulatory authorities in 25 countries of the European Union. Following EU and US submissions, Ipsen intends to implement worldwide submission roll-out.
- On **11 July 2014** – Ipsen and Galderma, a global healthcare company focused on dermatology and skin health, announced that they have significantly expanded the scope of their neurotoxin partnership. Under the terms of the agreement, the Dysport<sup>®</sup> distribution rights in the US and Canada, held originally by Valeant, have been included in the partnership between Ipsen and Galderma for the distribution of Dysport<sup>®</sup>/Azzalure<sup>®</sup> in aesthetic and dermatology indications. This partnership now covers the US, Canada, Brazil and Europe<sup>1</sup> for a period extending to 2036. As part of this renegotiated agreement, Galderma will pay €25 million to Ipsen and benefit from improved margins in those territories. Ipsen will manufacture and supply the finished product to Galderma and receive royalties from Galderma. In addition, the companies will increase the scope of their R&D collaboration through which each company will benefit from the other party's research compounds within its respective and exclusive areas of focus. In this regard, Ipsen will gain control of the intellectual property for Galderma's liquid toxin in the US, Canada, Brazil and Europe<sup>1</sup> in exchange for a €10 million payment, while Galderma retains commercialization rights.
- On **17 July 2014** – Ipsen announced that the New England Journal of Medicine has published clinical trial results showing that Somatuline<sup>®</sup> Autogel<sup>®</sup> / Somatuline<sup>®</sup> Depot<sup>®</sup> (lanreotide) Injection 120 mg (referred to as Somatuline<sup>®</sup>) achieved statistically significant prolongation of progression free survival over placebo in patients with metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs). CLARINET<sup>®</sup>, an investigational phase III randomized, double-blind, placebo-controlled study of the antiproliferative effects of Somatuline<sup>®</sup> was conducted in 48 centers across 14 countries. The article titled "Lanreotide in Metastatic Enteropancreatic Neuroendocrine Tumors" is available online at NEJM.org and has been published in the July 17<sup>th</sup> edition (N. Engl. J. Med. 2014; 371: 224-233). The data gathered from 204 GEP-NET patients over the 96-week study showed that placebo-treated patients had a median PFS of 18.0 months and 33.0% had not progressed or died at 96 weeks, whereas the median PFS for Somatuline<sup>®</sup> treated patients was not reached and 65.1% had not progressed or died at 96 weeks (stratified logrank test,  $p < 0.001$ ). This represented a 53% reduction in risk of disease progression or death based on a hazard ratio of 0.47 (95% CI: 0.30–0.73). These statistically and clinically significant antiproliferative effects of Somatuline<sup>®</sup> were observed in a large population of patients with grade G1 or G2 (World Health Organization classification) GEP-NETs, and independent of hepatic tumor volume ( $\leq 25\%$  or  $> 25\%$ ). Quality of life measures were not different between the Somatuline<sup>®</sup> and placebo groups. Safety data generated from the study are consistent with the known safety profile of Somatuline<sup>®</sup>.
- On **26 August 2014** – The North-American affiliate announced that a new supply of Increlex<sup>®</sup> would be available starting in September 2014. In collaboration with the U.S. Food and Drug Administration

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<sup>1</sup> Excluding Russia

(FDA), Ipsen released a second batch of Increlex<sup>®</sup> in 2014. The first batch was made available for distribution in June of 2014.

- On **1<sup>st</sup> September 2014** – Ipsen announced that the U.S. Food and Drug Administration (FDA) had accepted and granted priority review of its supplemental New Drug Application (sNDA) for Somatuline<sup>®</sup> Depot<sup>®</sup> 120mg injection in the treatment of gastroenteropancreatic neuroendocrine tumors (GEP-NETs). The FDA designates priority review status to drug candidates that have the potential to offer a significant improvement in treatment compared to currently approved options. Decision is expected in early Q1 2015. In the European Union, the dossier of the national marketing authorization variations for Somatuline<sup>®</sup> Autogel<sup>®</sup> 120mg injection has been validated by all national 25 drug regulatory authorities. The first decisions are expected by Q2 2015. The regulatory submissions and variations were supported by the results of the CLARINET<sup>®</sup> Phase III study, which demonstrated the antitumor effect of Somatuline<sup>®</sup> in the treatment of patients with GEP-NETs, and which was recently published in the July 17<sup>th</sup> issue of The New England Journal of Medicine.
- On **27 September 2014** – Ipsen announced the presentation at the ESMO 2014 Congress (26-30 September in Madrid) of the preliminary results of the phase II proof-of-concept clinical trial with tasquinimod in monotherapy, evaluating the compound in four advanced tumor types. The main objective of the study was to determine the clinical activity of tasquinimod in advanced hepatocellular (HCC), ovarian (OC), renal cell (RCC) and gastric (GC) carcinomas in patients who had progressed after standard anti-tumor therapies. Primary endpoint was the PFS rate at a predefined time for each cohort. Secondary objectives included PFS, response rate, OS, safety, pharmacokinetics and biomarkers. The data did not support further development of tasquinimod in monotherapy in heavily pretreated patients with advanced OC, RCC and GC. Pharmacokinetic and biomarkers analyses are ongoing. Preliminary results from the futility analysis reported sufficient clinical activity to complete the recruitment of the HCC cohort for which results are expected in 2015. The safety profile was consistent with the known safety profile of tasquinimod in previous studies.
- On **2<sup>nd</sup> October 2014** – Ipsen announced that Susheel Surpal would step down as Chief Financial Officer of Ipsen as of 31<sup>st</sup> October 2014 to pursue new opportunities.
- On **10 October 2014** – Ipsen announced the appointment of Aymeric Le Chatelier as Executive Vice President, Chief Financial Officer effective as of 3 November 2014. He will report directly to Marc de Garidel, Chairman and Chief Executive Officer and to Christel Bories, Deputy Chief Executive Officer. He will be a member of the Chairman Committee and of the Executive Committee.
- On **10 October 2014** – Ipsen announced positive results from the phase III study of triptorelin pamoate 11.25 mg (Decapeptyl<sup>®</sup> 3 months) administered subcutaneously in patients with locally advanced or metastatic prostate cancer at the European Association of Urology (EAU) 14th Central European Meeting in Cracow, Poland (10-12 October 2014). The primary objective of the study was to assess the efficacy and safety profile of the sustained-release triptorelin pamoate 11.25 mg (Decapeptyl<sup>®</sup> 3 months) formulation when administered by the subcutaneous route in men with locally advanced or metastatic prostate cancer. This objective was met with castration levels of testosterone achieved in 97.6% [95% CI: 93.2-99.5] of men at week 4 and castration maintained in 96.6% of these men [95% CI: 91.6-99.1] at week 26.
- On **22 October 2014** – Ipsen and Lexicon Pharmaceuticals, Inc. announced that they have entered into an exclusive licensing agreement for Ipsen to commercialize telotristat etiprate outside of North America and Japan, with a focus on the treatment of carcinoid syndrome. Lexicon retains sole rights to commercialize telotristat etiprate in the United States, Canada and Japan. Lexicon will continue to lead the global Phase 3 clinical program for telotristat etiprate in carcinoid syndrome, from which data are expected in 2015. The pivotal Phase 3 trial is comparing telotristat etiprate to placebo on a background of somatostatin analog (SSA) therapy, the current standard of care, in patients whose carcinoid syndrome is not adequately controlled with lanreotide or octreotide. The clinical Phase 3 study is recruiting in approximately 70 centers worldwide. Lexicon will continue to be responsible for the potential registration of telotristat etiprate in the U.S., Canada and Japan, while Lexicon and Ipsen will collaborate to seek regulatory approvals in Europe and other countries within the Ipsen licensed territory, with Ipsen assuming the lead responsibility in those markets. Under the financial terms of the agreement, Lexicon is eligible to receive up to \$145 million, comprising \$23 million upfront payment and additional payments contingent upon achievement of clinical, regulatory and commercial milestones. In addition, Lexicon is also eligible to receive royalties on net sales of telotristat etiprate in the licensed territory.

- On **6 November 2014** – Otonomy, Inc., a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapeutics for diseases and disorders of the inner and middle ear, and Ipsen, a global specialty-driven pharmaceutical company, announced that they have entered into an exclusive licensing agreement enabling Otonomy to utilize Ipsen's gacyclidine data in the development and registration of OTO-311. OTO-311 is Otonomy's sustained-exposure formulation of gacyclidine, an N-Methyl-D-Aspartate (NMDA) receptor antagonist, in development for the treatment of tinnitus.
- On **18 November 2014** – Ipsen and the Salk Institute for Biological Studies (Salk Institute) announced that they have agreed to renew their collaboration in medical sciences for another three years. The common objective for Ipsen and the Salk Institute is to achieve critical insights in the understanding of human diseases so as to develop new therapies for the treatment of patients afflicted with serious medical conditions.
- On **20 November 2014** – Ipsen and French National Center for Scientific Research (CNRS) announced the creation of the Archi-Pex (peptide architectures and formulations) joint research and innovation lab in collaboration with the French Alternative Energies and Atomic Energy Commission (CEA) and the University of Rennes 1. This is the result of a public-private partnership active since 1999. The joint Archi-Pex lab, supported by the French National Research Agency, seeks to conduct multi-disciplinary research bringing together academic teams in physics and biology with the researchers at Ipsen's center for pharmaceutical development based in Dreux (France). The aim is to innovate in the formulation of hormonal peptides and to reduce the development time. Understanding of the pharmaceutical efficacy arising from basic knowledge is the key to Archi-Pex project.
- On **28 November 2014** – Ipsen announced that the U.S. Food and Drug Administration (FDA) has accepted for review its supplemental Biologics License Application (sBLA) for Dysport® (abobotulinumtoxinA) in the treatment of upper limb spasticity in adult patients. The regulatory filing was based on a clinical Phase III study involving nearly 250 adult patients with upper limb spasticity. The international, multi-center, double-blind, randomized, placebo controlled trial compared the efficacy of Dysport® versus placebo in hemiparetic patients following a stroke or brain trauma. The data showed that those treated with Dysport® demonstrated a statistically significant ( $p < 0.0001$ ) improvement in muscle tone and a higher clinical benefit, versus placebo. The safety profile observed in the study was consistent with the known safety profile of Dysport®.
- On **12 December 2014** – Ipsen announced that the International Breast Cancer Study Group (IBCSG) presented results of the randomized phase III SOFT clinical trial at the 2014 San Antonio Breast Cancer Symposium. Suppression of Ovarian Function Trial (SOFT) assessed the value of ovarian suppression in reducing breast cancer recurrence in young women receiving tamoxifen, and evaluated the role of the aromatase inhibitor exemestane plus ovarian suppression in this population. Ovarian suppression was obtained entirely by monthly injections of triptorelin (active ingredient of Ipsen's Decapeptyl®) over 5 years for 81% of patients. Treatment combining tamoxifen plus ovarian suppression reduced the relative risk of developing invasive breast cancer recurrence by 22% in women who did not transition into menopause after receiving chemotherapy, when compared to treatment with tamoxifen alone.
- On **16 December 2014** – François Garnier has been appointed Executive Vice President, General Counsel for the Ipsen Group effective as of January 5, 2015. As such, he will sit on the Chairman's Committee and on the Executive Committee.
- On **16 December 2014** – Ipsen announced that Somatuline® Depot® (lanreotide) Injection 120 mg (referred to as Somatuline®) was approved by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs). Somatuline's approval was based on demonstration of improved progression-free survival (PFS) in CLARINET® multi-center, international, randomized (1:1), double-blind, placebo controlled study that enrolled 204 patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic, non-functioning GEP-NETs. Patients were randomized to receive either Somatuline® (lanreotide) 120 mg or placebo subcutaneously every 28 days. The primary efficacy endpoint was PFS as determined by independent central radiology review. The trial demonstrated a significant prolongation of PFS for the Somatuline® (lanreotide) arm [HR 0.47 (95% CI: 0.30, 0.73);  $p < 0.001$ ; stratified log-rank test]. The median PFS in the Somatuline® (lanreotide) arm had not been reached at the time of the final analysis and therefore is greater than 22 months. The median PFS in the placebo arm was 16.6 months. Safety data were

evaluated in 101 patients who received at least one dose of Somatuline<sup>®</sup> (lanreotide). The most commonly (greater than or equal to 10%) reported adverse reactions in Somatuline<sup>®</sup> (lanreotide)-treated patients were abdominal pain, musculoskeletal pain, vomiting, headache, injection site reaction, hyperglycemia, hypertension, and cholelithiasis. The most common serious adverse reaction of Somatuline<sup>®</sup> (lanreotide) observed in this trial was vomiting (4%).

After **31 December 2014**, major developments included:

- On **26 January 2015** – Ipsen announced topline results for two double-blind phase III studies of Dysport<sup>®</sup> (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<sup>®</sup> 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<sup>®</sup> 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. Other spasticity and functional outcome results are currently being analyzed. The safety profile observed in the studies was consistent with the known safety profile of Dysport<sup>®</sup> in these indications. Comprehensive results from these double-blind studies will be disclosed in the next few months at major international congresses. Ipsen will share these results with key regulatory agencies this year.

## 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 2014. In addition, certain measures introduced in 2013 have continued to affect the Group's accounts year-on-year.

### Measures that have impacted 2014

#### In the Major Western European countries:

- In France, the price of Smecta<sup>®</sup> was cut by 7.5% as of 1<sup>st</sup> July 2014, following a first price cut of the same magnitude as of 1<sup>st</sup> January 2014. Moreover, health authorities have required a 4.0% price cut on Decapeptyl<sup>®</sup> as of 1<sup>st</sup> April 2014;
- In the UK, Decapeptyl<sup>®</sup> has been sold at 100.0% of the NHS (*National Health Service*) price since March 2014.

#### In the Other European countries:

- In Belgium, Dysport<sup>®</sup> experienced a 2.4% price decrease as of January 2015 as the product has been reimbursed for more than 15 years in the market. In Luxemburg, Dysport<sup>®</sup> will be impacted by the same decrease as the country references the Belgium price;
- In Czech Republic, as of October 2014, the Ministry of Health decided to increase drug prices to compensate for the Czech Kroun devaluation. Ipsen benefited from a price increase of around 7.0% on all its products;
- In Denmark, in May 2014, the DHMA (*The Danish Health and Medicines Authority*) granted a 50.0% price increase on Increlex<sup>®</sup>, based on the Pharmacist Purchase Price;
- In Estonia, the Ministry of Health decreased the price of Decapeptyl<sup>®</sup> 1M by 9.7% following application of international reference pricing. However, the reimbursement rate increased to 100.0% from 50.0% for use as adjuvant therapy to radiotherapy;
- In Greece, the €2.44 billion claw-back introduced end of 2013 has not been readjusted by the Ministry of Health as initially anticipated. Health authorities are targeting €2 billion for 2014. Decapeptyl<sup>®</sup> was impacted by a significant increase in patient co-payment. In addition, since 1<sup>st</sup> April 2014, the Ministry of Health has recognized the difference between biological products, biosimilars and generics. It will therefore not be possible for these different product types to be part of common tenders;
- In Italy, Hexvix<sup>®</sup> experienced a 13.0% price cut in February 2014 after it became eligible for reimbursement at the national level;
- In Lithuania, Somatuline<sup>®</sup> was granted national reimbursement in April 2014 in the acromegaly indication;
- In Poland, Decapeptyl<sup>®</sup> and Somatuline<sup>®</sup> have been affected by a price revision applicable as of 1<sup>st</sup> January 2014. Dysport<sup>®</sup> obtained reimbursement in spasticity indications, effective from July 2014 to July 2016. In Primary Care, the price of Fortrans<sup>®</sup> increased by 10.0% in September 2014 following strong support from the Polish Endoscopy Medical Society;
- In Portugal, the Ministry of Health is pressing the local pharmaceutical association (APIFARMA) in the context of negotiations with the industry on the spending exceeding a certain threshold in 2014. For the 2015 government budget, the Ministry of Finance contemplates the introduction of an extraordinary tax with a particular attention to pharmaceutical industry profits;
- In the Netherlands, the application of international reference pricing led to a price decrease on NutropinAq<sup>®</sup> and to price increases on Somatuline<sup>®</sup>, Dysport<sup>®</sup> and Decapeptyl<sup>®</sup> as of 1<sup>st</sup> April 2014. Somatuline<sup>®</sup> benefited from a second price increase as of 1<sup>st</sup> October 2014;

- In Norway, the December 2013 review of international reference pricing led to price cuts on Dysport® and NutropinAq®, and to a price increase on Somatuline®. In addition, Somatuline® benefited from a price increase in November 2014 following the application of international reference pricing;
- In Slovakia, in April 2014, Ipsen submitted prices for the second yearly revision based on the average 3 lowest prices in EU 28. This led to price decreases on all Ipsen products;
- In Slovenia, the official price of Dysport® was cut in June 2014 to be aligned with the reimbursed price;
- In Sweden, since January 2014, products that have been marketed for more than 15 years (notably Decapeptyl®) are subject to a mandatory price cut of 7.5%. In June 2014, TLV (*The Dental and Pharmaceutical Benefits Agency*) granted a 25.0% price increase on the Pharmacist Purchase Price to Increlex®;
- In Switzerland, Dysport® was impacted by a price cut in December 2013 following the application of international reference pricing;

#### **In the Rest of the World:**

- In Brazil, products with no generics on the market benefited from a 1.0% price increase in 2014;
- In Colombia, the “National Committee of Drug Prices” (*Comisión Nacional de Precios de Medicamentos*) imposed a price cut on 364 medicines in December 2013, including Dysport®. In August 2013, the prices of 195 medicines had already been regulated, including Somatuline®;
- In China, the NDRC (National Development & Reform Commission) issued a “Low-Price Drug List” in May 2014 to align the prices of all ginkgo biloba tablets. However, Tanakan® is excluded from this list and will keep its original retail price;
- In Turkey, due to a revision of international reference pricing in September 2014, the price of Somatuline® was raised. However, the mandatory rebate on the reimbursement price was also raised.

Furthermore, and 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 2014.

#### **Measures impacting beyond 2014**

##### **In the Major Western European countries:**

- In France, the 2014 Social Security Finance Bill (PLFSS) was introduced, with the possibility for the first time for the pharmacist to substitute biotechnology products by biosimilars, except when forbidden by the physician on the prescription. This rule was not enforced yet, pending the publication of a decree. In addition, the French 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 fixed at 2.1% year-on-year, down from 2.4% in 2014. This is expected to result in €3.2 billion savings. In addition, Decapeptyl® will experience a 3.0% price decrease as of 1<sup>st</sup> January 2015. Finally, the two Smecta® price cuts will fully impact countries that reference French prices (incl. European Union, sub-Saharan Africa) in 2015;
- In Germany, the mandatory sales rebate for the official price of prescription drugs, initially set at 16.0%, was reduced to 7.0% as of 1<sup>st</sup> January 2014;
- In Spain, the final Royal Decree List arising from the implementation of the Reference Price System was published on 15 July 2014. As a result, the official published prices of Decapeptyl® and Dysport® will be affected. Additionally, the mandatory rebate of 15.0% applicable on the official price of Decapeptyl® was canceled;
- In the UK, the new PPRS (*Pharmaceutical Price Regulation Scheme*) was implemented, with the option for pharmaceutical companies to apply a 5.0% to 7.0% price cut on the NHS (*National Health Service*) selling price modulated over the whole portfolio, or the option to reimburse this amount through pay back. Moreover, since January 2014, tenders are managed at the regional level instead of the hospital level.

### **In the Other European countries:**

- In Bulgaria, the Ministry of Health published a new ordinance to extend the limitation of price increases of over-the-counter (OTC) medicines to 1.0% for another year;
- In Czech Republic, the Parliament approved the introduction of a reduced VAT rate on medicines, down to 10.0% from 21.0% as of 2015. The reduced VAT rate will have a positive impact on access to medicines;
- In Croatia, Czech Republic replaced France in the basket of countries included in the international reference pricing system;
- In Kazakhstan, pressurized to address corruption issues, the Ministry of Healthcare and Social Development will amend the methodology and mechanism for price determination, hence increasing transparency within government procurement process. It intends to create a national drug formulary that will include maximum pricing for medications with proven clinical efficacy and for brands within the context of international non-proprietary name (INN);
- In Ukraine, the Ministry of Health published a draft resolution that introduces Internal and External Reference Pricing for prescription drugs and for medicines procured through state funds. Rule will be to take the average price of the countries of origin: Bulgaria, the Czech Republic, Hungary, Latvia, Moldova, Poland, Serbia, Slovakia. This development reflects the intent of the Ukrainian government to monitor drug prices, notably given the average price rise of 16.0% reported this year, resulting from the “anti-crisis” measures (currency devaluation and implementation of a 7.0% VAT on drug prices as of 1<sup>st</sup> April 2014). The potential state price regulation would reportedly affect 10,000 drugs, or approximately 80.0% of the market, with the maximum margin on bulk purchases being 10.0%, and retail mark-up of 25.0%;

### **In the Rest of the World:**

- In Algeria, marketing authorisations for the Primary Care portfolio were renewed. In addition, Smecta<sup>®</sup> “localization” has successfully undergone review from the Algerian Price Committee. Ipsen secured a price for the next 5 years and price revision will only occur when a Smecta<sup>®</sup> generic is approved. In the context of the sharp and continuous decline in oil prices, authorities are looking at drastically reducing import costs, as of January 2015. This will impact pharmaceuticals which account for €3 billion in the state budget;
- In South Africa, the Department of Health published draft legislation governing pricing of novel drugs in the country. The guidelines set forth a potential international reference pricing system. No timeline for advancement is known yet;
- In China, the NDRC (National Development & Reform Commission) will deregulate the national drug pricing system from 2015. It will theoretically allow the free setting of drug prices, rather than forcing companies to adhere to government regulated price caps on drug retail prices. However, local government tender centers will keep control over the bidding price, which is the price to patients plus the hospital margin;
- In Morocco, the Ministry of Health is looking at lowering the prices of several ranges of medications. This will affect drugs used for the treatment of various chronic conditions, including cardiovascular diseases, diabetes, inflammatory, infectious, digestive diseases, as well as some cancer drugs and treatments for benign prostatic hyperplasia;
- In Tunisia, the creation of a National Medicines Agency (“*Agence nationale du Médicament*”) is at an advanced stage of preparation. The Ministry of Health updated existing texts on regulatory and clinical requirements so as to meet the highest international standards;
- In Turkey, authorities are thinking of introducing a flexible price system in 2014. The exact content is not yet known but measures such as not including countries under Troika (countries where policies are imposed by the European Commission, the European Central Bank and the International Monetary Fund), an update of foreign exchange rates, and a price increase for products under shortage, are currently under consideration.

## Comparison of consolidated sales for the four quarters and full years 2014 and 2013:

### Sales by therapeutic area and by product

Note: Unless stated otherwise, all variations in sales are stated excluding foreign exchange impacts and are computed by restating the 2013 sales with the 2014 exchange rates.

The following table shows sales by therapeutic area and by product for the fourth quarters and full years 2014 and 2013:

(in million euros)	4 <sup>th</sup> quarter				12 months			
	2014	2013	% Variation	% Variation at constant currency	2014	2013	% Variation	% Variation at constant currency
Urology-oncology	77.1	79.5	-2.9%	-3.7%	332.7	313.0	6.3%	6.7%
of which Hexvix®	3.9	3.7	6.2%	6.0%	16.0	14.4	11.4%	11.1%
of which Decapeptyl®	73.2	75.8	-3.4%	-4.2%	316.6	298.6	6.0%	6.5%
Endocrinology	92.2	74.5	23.8%	21.7%	359.4	315.9	13.8%	14.0%
of which Somatuline®	73.9	60.3	22.5%	20.6%	287.5	246.9	16.4%	16.8%
of which NutropinAq®	13.9	14.0	-0.3%	-0.7%	59.0	56.3	4.9%	4.9%
of which Increlex®	4.4	0.2	2029.0%	865.8%	12.9	12.7	1.4%	1.3%
Neurology	59.4	55.9	6.4%	8.2%	255.0	242.2	5.3%	8.8%
of which Dysport®	59.2	55.9	5.9%	7.7%	254.5	242.2	5.1%	8.6%
<b>Specialty care</b>	<b>228.8</b>	<b>209.9</b>	<b>9.0%</b>	<b>8.5%</b>	<b>947.1</b>	<b>871.1</b>	<b>8.7%</b>	<b>9.9%</b>
Gastroenterology	52.6	51.6	1.8%	2.4%	219.3	219.9	-0.3%	2.2%
of which Smecta®	26.8	28.9	-7.3%	-7.3%	121.4	121.1	0.2%	2.7%
of which Forlax®	10.1	9.3	9.1%	9.1%	38.5	38.7	-0.7%	0.0%
Cognitive disorders	15.0	18.5	-18.7%	-9.7%	62.6	67.2	-6.8%	-0.6%
of which Tanakan®	15.0	18.5	-18.7%	-9.7%	62.6	67.2	-6.8%	-0.6%
Cardiovascular	3.6	3.9	-6.9%	-6.6%	18.7	20.6	-9.1%	-8.8%
of which Nisis® & Nisisco®	1.6	1.8	-12.1%	-12.1%	6.5	7.8	-15.9%	-15.9%
of which Ginkor®	1.7	1.6	1.0%	1.5%	11.2	11.7	-4.4%	-3.8%
Other Primary Care	3.0	3.6	-15.7%	-14.2%	11.3	12.5	-9.6%	-8.9%
of which Adrovan®	2.1	2.6	-16.4%	-16.4%	9.1	10.4	-12.6%	-12.6%
<b>Primary care</b>	<b>74.2</b>	<b>77.5</b>	<b>-4.3%</b>	<b>-1.5%</b>	<b>311.9</b>	<b>320.2</b>	<b>-2.6%</b>	<b>0.5%</b>
<b>Total Drug Sales</b>	<b>303.0</b>	<b>287.4</b>	<b>5.4%</b>	<b>5.9%</b>	<b>1259.0</b>	<b>1 191.3</b>	<b>5.7%</b>	<b>7.4%</b>
<b>Drug-related Sales*</b>	<b>4.1</b>	<b>5.6</b>	<b>-27.5%</b>	<b>-28.5%</b>	<b>15.9</b>	<b>33.5</b>	<b>-52.7%</b>	<b>-53.0%</b>
<b>Group Sales</b>	<b>307.1</b>	<b>293.0</b>	<b>4.8%</b>	<b>5.2%</b>	<b>1274.8</b>	<b>1 224.8</b>	<b>4.1%</b>	<b>5.7%</b>

\*Active ingredients and raw materials

In the fourth quarter 2014, sales of **Specialty care** products reached €228.8 million, up 8.5% year-on-year. In 2014, sales amounted to €947.1 million, up 9.9%. Sales in urology-oncology, endocrinology, and neurology grew by respectively 6.7%, 14.0% and 8.8%. In 2014, the relative weight of specialty care products continued to increase to reach 74.3% of total Group sales, compared to 71.1% the previous year.

In **Urology-oncology**, sales of **Decapeptyl**<sup>®</sup> reached €73.2 million in the fourth quarter 2014, down 4.2% year-on-year, and €316.6 million for the full year 2014, up 6.5%. Sales growth in 2014 benefited from a favorable comparison base weak product performance in the first nine months 2013 in China and in the Middle East, where Ipsen had limited the supply of its products due to the absence of payment guarantees, but was penalized in the fourth quarter 2014 by the strong pick-up in sales in these regions in the fourth quarter 2013. In 2014, **Decapeptyl**<sup>®</sup> performance nonetheless took place in a contracting pharmaceutical market in Europe, notably impacted by a more frequent use of co-payment in Southern Europe and a slowdown in the growth of Eastern European countries. As such, performance in France suffered from a decrease in volumes sold and from the implementation of a 4.0% price cut as of 1<sup>st</sup> April 2014. In 2014, sales of **Hexvix**<sup>®</sup> amounted to €16.0 million, up 11.1% compared to 2013, mainly generated in Germany. Over the period, sales in Urology-oncology represented 26.1% of total Group sales, compared to 25.6% the previous year.

In **Endocrinology**, sales reached €92.2 million in the fourth quarter 2014, up 21.7% year-on-year. In 2014, sales amounted to €359.4 million, up 14.0%, and represented 28.2% of total Group sales, compared to 25.8% the previous year.

**Somatuline**<sup>®</sup> – In the fourth quarter 2014, sales reached €73.9 million, up 20.6% year-on-year. In 2014, sales of **Somatuline**<sup>®</sup> grew 16.8% to €287.5 million, driven by strong volume and value growth in the United States, strong volume growth in Germany together with a reduction (from 16% to 7%) in mandatory rebates on prescription drug sales, and solid volume momentum in the United Kingdom. **Somatuline**<sup>®</sup> recorded good performance in Spain, France, the Netherlands, Denmark and Belgium, and was penalized by a price cut in Columbia.

**NutropinAq**<sup>®</sup> – In the fourth quarter 2014, sales reached €13.9 million, down 0.7% compared to the same period in 2013. In 2014, sales of **NutropinAq**<sup>®</sup> amounted to €59.0 million, up 4.9% year-on-year, driven by good performance in Germany and France.

**Increlex**<sup>®</sup> – In the fourth quarter 2014, sales reached €4.4 million, up sharply compared to the same period in 2013, helped by a favorable base effect arising from the shortage situation that 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 2014, sales of **Increlex**<sup>®</sup> amounted €12.9 million, up 1.3% year-on-year.

In **Neurology**, **Dysport**<sup>®</sup> sales reached €59.2 million in the fourth quarter 2014, up 7.7% year-on-year. In 2014, **Dysport**<sup>®</sup> sales amounted to €254.5 million, up 8.6%, driven by the supply of the product to Galderma for aesthetic use and by the solid volume performance of the therapeutic and aesthetic segments in Brazil. Growth was affected by the intensification of competitive intensity in South Korea and United Kingdom, while benefiting in Germany from the reduction in mandatory rebates. Neurology sales represented 20.0% of total Group sales in 2014, compared to 19.8% a year earlier.

In the fourth quarter 2014, sales of **Primary care** products reached €74.2 million, down 1.5% year-on-year. In 2014, sales amounted to €311.9 million, up 0.5%. In France, sales of Primary care products declined 9.9%, affected by two price cuts on **Smecta**<sup>®</sup> and the launch of a competing product to **Tanakan**<sup>®</sup> in March 2013. Internationally, sales increased 5.2%, driven by solid performance in China, Algeria and Russia, offsetting the decline in France. Primary care sales in France accounted for 27.8% of the Group's total primary care sales, compared to 30.1% the previous year.

In **Gastroenterology**, sales reached €52.6 million in the fourth quarter 2014, up 2.4% year-on-year. In 2014, sales amounted to €219.3 million euros, up 2.2% compared to 2013.

**Smecta**<sup>®</sup> – In the fourth quarter 2014, sales reached €26.8 million, down 7.3% year-on-year, mainly affected by the interruption of direct sales in Algeria, replaced from now on by the sales of the active principle to a local manufacturer, which are recorded in Drug-related sales. Restated for this item, sales increased 1.8% over the quarter. In 2014, sales amounted to €121.4 million euros, up 2.7%, driven by solid growth in Russia, Algeria and China, but affected in France by the two 7.5% price cuts implemented in January and July 2014 and a low level of gastroenteritis epidemic compared to last year. **Smecta**<sup>®</sup> sales represented 9.5% of total Group sales over the period, compared to 9.9% the previous year.

**Forlax®** – In the fourth quarter 2014, sales reached €10.1 million, up 9.1% year-on-year. In 2014, sales amounted to €38.5 million euros, flat year-on-year, affected by the reinforcement of the “Tiers-Payant<sup>1</sup>” regulation in France and by the lower sales to our partners marketing generic versions of the product. In 2014, France represented 45.4% of total product sales, compared to 48.2% the previous year.

In the **cognitive disorders area**, sales of **Tanakan®** reached €15.0 million euros in the fourth quarter 2014, down 9.7% year-on-year. In 2014, sales amounted to €62.6 million euros, down 0.6%, driven by the good performance of the product in Russia. The product’s growth was penalized by the launch of a second “me-too” product in France in 2013 and by a change in the commercial model for Spain, where the product is now distributed by a partner. In 2014, 22.7% of Tanakan® sales were achieved in France, compared to 24.3% the previous year.

**In the cardiovascular area**, sales reached €3.6 million euros in the fourth quarter 2014, down 6.6% year-on-year. In 2014, sales amounted to €18.7 million euros, down 8.8% over the period, mainly impacted by the decline of **Nisis® / Nisisco®** sales, which suffered from a 12.5% price cut in October 2013.

Sales of **Other primary care** products reached €3.0 million in the fourth quarter 2014, down 14.2% year-on-year. In 2014, sales amounted to €11.3 million, down 8.9%, mainly affected by the 12.6% decline in **Adavance®** sales.

In the fourth quarter 2014, **drug-related sales (active ingredients and raw materials)** reached €4.1 million, down 28.5% year-on-year. In 2014, sales amounted to €15.9 million euros, down 53.0%. Performance was notably explained by an unfavourable effect associated with the change in methodology for the consolidation of sales of the Swiss company Linnea. Indeed, sales of active ingredients and raw materials made by Linnea, partner on which Ipsen and the Schwabe Group exercise joint control, will from now on be consolidated under the equity method of accounting<sup>2</sup>. Restated for this base effect, sales declined 11.3%, affected by Ginkgo Biloba extracts and a decline in diomagnite orders in Egypt and Korea, where local partners have liquidity issues and margin erosion due to price cuts in the market.

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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

<sup>2</sup> In accordance with the norm IFRS11 « Partnerships » that came into force as of 1<sup>st</sup> January 2014 on the accounting treatment of joint ventures

## Sales by geographical area

Group sales by geographical area in the fourth quarters and and full years 2014 and 2013:

(in million euros)	4 <sup>th</sup> quarter				12 months			
	2014	2013	% Variation	% Variation at constant currency	2014	2013	% Variation	% Variation at constant currency
France	53.4	52.7	1.3%	1.3%	211.4	218.0	-3.0%	-3.0%
Germany	23.6	20.6	14.8%	14.8%	94.2	84.1	12.0%	12.0%
Italy	17.8	18.8	-5.4%	-5.4%	78.5	81.3	-3.4%	-3.4%
United Kingdom	17.8	15.4	15.6%	8.7%	65.1	57.3	13.5%	7.7%
Spain	15.6	14.0	11.4%	11.4%	59.9	56.6	5.8%	5.8%
<b>Major Western European countries</b>	<b>128.2</b>	<b>121.5</b>	<b>5.5%</b>	<b>4.7%</b>	<b>509.1</b>	<b>497.3</b>	<b>2.4%</b>	<b>1.8%</b>
Eastern Europe	43.0	49.2	-12.5%	2.3%	177.1	184.9	-4.2%	4.8%
Others Europe	36.8	34.4	7.1%	7.4%	147.0	144.5	1.7%	2.1%
<b>Other European Countries</b>	<b>79.9</b>	<b>83.6</b>	<b>-4.4%</b>	<b>4.6%</b>	<b>324.1</b>	<b>329.4</b>	<b>-1.6%</b>	<b>3.6%</b>
<b>North America</b>	<b>21.2</b>	<b>14.2</b>	<b>49.4%</b>	<b>36.3%</b>	<b>79.2</b>	<b>64.2</b>	<b>23.2%</b>	<b>23.7%</b>
Asia	46.0	41.8	10.1%	1.7%	190.5	177.3	7.4%	7.7%
Other countries in the Rest of the world	31.8	32.0	-0.6%	-1.5%	172.0	156.5	9.9%	13.6%
<b>Rest of the World</b>	<b>77.8</b>	<b>73.8</b>	<b>5.4%</b>	<b>0.4%</b>	<b>362.5</b>	<b>333.9</b>	<b>8.6%</b>	<b>10.4%</b>
<b>Group Sales</b>	<b>307.1</b>	<b>293.0</b>	<b>4.8%</b>	<b>5.2%</b>	<b>1274.8</b>	<b>1 224.8</b>	<b>4.1%</b>	<b>5.7%</b>
<b>Of which: Total Drug Sales</b>	<b>303.0</b>	<b>287.4</b>	<b>5.4%</b>	<b>5.9%</b>	<b>1259.0</b>	<b>1 191.3</b>	<b>5.7%</b>	<b>7.4%</b>
<b>Drug-related Sales*</b>	<b>4.1</b>	<b>5.6</b>	<b>-27.5%</b>	<b>-28.5%</b>	<b>15.9</b>	<b>33.5</b>	<b>-52.7%</b>	<b>-53.0%</b>

\* Active ingredients and raw materials

In the fourth quarter 2014, sales generated in the **Major Western European countries** reached €128.2 million, up 4.7% year-on-year. In 2014, sales amounted to €509.1 million, up 1.8%. Sales in the Major Western European countries represented 39.9% of total Group sales in 2014, compared to 40.6% the previous year.

**France** – In the fourth quarter 2014, sales reached €53.4 million, up 1.3% year-on-year. In 2014, sales amounted to €211.4 million, down 3.0%, affected by the decline of primary care sales. Sales of Smecta<sup>®</sup> decreased over the period, penalized by the low level of gastroenteritis epidemic compared to last year and by two 7.5% price cuts implemented in January and July 2014. Moreover, sales of Forlax<sup>®</sup> suffered from generics competition while Tanakan<sup>®</sup> continued to be impacted by the launch of a second “me-too” product in March 2013. Sales of specialty care products, up 2.6% over the period, were driven by the sustained growth of Somatuline<sup>®</sup> and NutropinAq<sup>®</sup> sales, but penalized by the decrease in Decapeptyl<sup>®</sup> sales, both in volume and value following the 4.0% price cut implemented as of 1<sup>st</sup> April 2014. Consequently, the relative weight of France in the Group’s consolidated sales has continued to decrease and now represents 16.6% of sales, compared to 17.8% the previous year.

**Germany** – In the fourth quarter 2014, sales reached €23.6 million, up 14.8% year-on-year. In 2014, sales reached €94.2 million, up 12.0%. The favorable impact associated with the reduction (from 16% to 7%) in mandatory rebates on prescription drug sales and the strong volume growth of Somatuline<sup>®</sup> and Hexvix<sup>®</sup> offset the reduction in the supply of Ginkgo Biloba extracts to our partner Schwabe. Over the period, sales in Germany represented 7.4% of total Group sales, compared to 6.9% a year earlier.

**Italy** – In the fourth quarter 2014, sales reached €17.8 million, down 5.4% year-on-year. In 2014, sales reached €78.5 million, down 3.4%. The growth of Somatuline<sup>®</sup> was not enough to offset the impact of austerity control measures targeting hospital products. In 2014, Italy represented 6.2% of consolidated Group sales, compared to 6.6% the previous year.

**United Kingdom** – In the fourth quarter 2014, sales reached €17.8 million, up 8.7% year-on-year. In 2014, sales amounted to €65.1 million, up 7.7%, fueled by the strong volume growth of Somatuline<sup>®</sup> and Decapeptyl<sup>®</sup>, but affected by the decline in Dysport<sup>®</sup> sales. In 2014, the United Kingdom represented 5.1% of total Group sales, compared to 4.7% the previous year.

**Spain** – In the fourth quarter 2014, sales reached €15.6 million, up 11.4% year-on-year. In 2014, sales amounted to €59.9 million, up 5.8%, driven by double-digit growth of Somatuline<sup>®</sup> sales but affected by a change in the commercial model for Tanakan<sup>®</sup>, for which revenues are no longer recorded in the sales line. In 2014, Spain accounted for 4.7% of total Group sales, compared to 4.6% the previous year.

In the fourth quarter 2014, sales generated in the **Other European countries** reached €79.9 million, up 4.6% year-on-year, affected by lower sales in Russia, where current geopolitical context is tense. In 2014, sales amounted to €324.1 million, up 3.6%, affected by an unfavorable effect arising from the change in methodology for the consolidation of sales of the Swiss company Linnea. Indeed, sales of active ingredients and raw materials made by Linnea, partner on which Ipsen and the Schwabe Group exercise joint control, will from now on be consolidated under the equity method of accounting<sup>1</sup>. Restated for this base effect, sales grew 9.1%, mainly driven by the good performance of Tanakan<sup>®</sup> in Russia, following a media campaign and the implementation of a new distribution scheme as of 1<sup>st</sup> April 2014. Sales were also driven by the supply of Dysport<sup>®</sup> for aesthetic use to Galderma, as well as the solid performance of the Netherlands, Turkey, Denmark, and Belgium. Sales were impacted by the consequences of the political crisis ongoing in Ukraine. In 2014, sales in this region represented 25.4% of consolidated Group sales, compared to 26.9% the previous year.

In the fourth quarter 2014, sales generated in **North America** reached €21.2 million, up 36.3% year-on-year, driven by the resumption of Increlex<sup>®</sup> supply in June 2014, and the strong 30.5% growth of Somatuline<sup>®</sup>. In 2014, sales amounted to €79.2 million, up 23.7%, driven by the solid growth of Somatuline<sup>®</sup> in both volume and value and the exceptional orders made by Galderma in aesthetic medicine in the third quarter, but affected by the supply interruption of Increlex<sup>®</sup> in the first half of the year. Restated for the Increlex<sup>®</sup> supply interruption, sales increased 31.6% in 2014. Sales in North America represented 6.2% of consolidated Group sales, compared to 5.2% a year earlier.

In the fourth quarter 2014, sales generated in the **Rest of the World** reached €77.8 million, up 0.4% year-on-year. In 2014, sales amounted to €362.5 million, up 10.4%, boosted by a favourable base effect in the Middle East, where Ipsen had stopped supplying its products in certain countries of the region in 2013 due to the absence of payment guarantees. Sales growth in the Rest of the World mainly arose from strong volume growth in China and Algeria (notably of Decapeptyl<sup>®</sup> and Smecta<sup>®</sup>), and in Brazil, where Dysport<sup>®</sup> recorded good performance in aesthetic and therapeutic medicines. In 2014, sales in the Rest of the World have continued their progression to reach 28.4% of total consolidated Group sales, compared to 27.3% the previous year.

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<sup>1</sup> In accordance with the norm IFRS11 « Partnerships » applicable since 1<sup>st</sup> January 2014 on the accounting treatment of joint ventures