

# Ipsen's first quarter 2014 sales

- Group sales up 2.4%<sup>1</sup>
- Solid specialty care growth, up 6.4%<sup>1</sup>
- Somatuline® and Dysport® up 13.0%¹ and 6.3%¹, respectively
- Decapeptyl<sup>®</sup> up 5.9%<sup>1</sup>, driven by improving performance in China
- Primary care down 1.7%<sup>1</sup>, fueled by strong international growth in a still challenging French context

Paris (France), 30 April 2014 - Ipsen (Euronext: IPN; ADR: IPSEY) reported today its sales for the first quarter 2014.

First guarter 2014 unaudited IFRS consolidated sales

(in million euros)	2014	2013	% Change	% Change at constant currency
SALES BY REGION				
Major Western European countries	129.3	127.6	1.3%	1.0%
Other European countries	81.6	81.7	-0.2%	4.5%
North America	14.3	17.3	-17.0%	-14.0%
Rest of the world	80.8	80.1	0.9%	6.1%
Group Sales	305.9	306.6	-0.2%	2.4%
SALES BY THERAPEUTIC AREA				
Specialty care	225.3	217.0	3.8%	6.4%
Primary care	76.6	80.4	-4.7%	-1.7%
Total Drug Sales	301.9	297.3	1.5%	4.3%
Drug-related sales <sup>2</sup>	4.1	9.3	-56.3%	-56.4%
Group Sales	305.9	306.6	-0.2%	2.4%

Commenting on the first quarter 2014 performance, Marc de Garidel, Chairman and Chief Executive Officer of Ipsen said: "Ipsen is off to a good start this year with solid specialty care growth, up 6.4%1, notably driven by the good performance of Somatuline® and Dysport® and the return to growth of Decapeptyl® in China. Moreover, Primary Care, negatively impacted by a continuous decline in France, benefited from strong international growth." Marc de Garidel added: "The Group is paying special attention to the potential consolidations that may alter the competitive landscape in its areas of interest."

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

<sup>&</sup>lt;sup>2</sup> Drug related sales correspond to sales of active indredients and raw materials



### First quarter 2014 sales highlights

Note: Unless stated otherwise, all variations in sales are stated excluding foreign exchange impacts by restating the Q1 2013 sales with the Q1 2014 exchange rates.

Consolidated Group sales reached €305.9 million in the first guarter 2014, up 2.4% year-on-year.

**Drug sales** reached €301.9 million in the first quarter 2014, up 4.3% year-on-year, fueled by the sales growth of **Specialty Care** products, up 6.4% year-on-year. Sales in Uro-oncology, Endocrinology, and Neurology grew by respectively 6.1%, 6.9% and 6.3% year-on-year. In the first quarter 2014, the relative weight of specialty care products continued to increase to reach 73.6% of total Group sales, compared to 70.8% the previous year.

Sales of **Primary Care** products amounted to €76.6 million, down 1.7% year-on-year. Sales recorded solid performance in China, Russia, and Algeria. Sales in France declined by 15.3% year-on-year, affected by the launch of a competitive product to Tanakan® in March 2013, the 7.5% price cut on Smecta® implemented as of 1<sup>st</sup> January 2014, and the negative consequences arising from the reinforcement of the "Tiers-Payant<sup>1</sup>" regulation.

Sales generated in the **Major Western European countries** amounted to €129.3 million, up 1.0% year-on-year. The dynamic growth of specialty care products was partially offset by the decline of French primary care sales. Sales in the Major Western European countries represented 42.2% of total Group sales in the first quarter 2014, compared to 41.6% the previous year.

Sales generated in the **Other European countries** reached €81.6 million, up 4.5% year-on-year, penalized 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>2</sup>. Restated for this base effect, sales were up 10.2%. Moreover, sales were driven by solid volume growth in Russia, where Dysport<sup>®</sup> continues to penetrate the aesthetics and therapeutics markets and where Tanakan<sup>®</sup> records strong growth, the supply of Dysport<sup>®</sup> for aesthetic use to Galderma, and the solid performance of the Netherlands and the Czech Republic. Sales were penalized by the consequences of the political crisis ongoing in Ukraine. In the first quarter 2014, sales in this region represented 26.7% of consolidated Group sales, a stable ratio year-on-year.

Sales generated in **North America** reached €14.3 million, down 14.0% year-on-year, mainly impacted by the Increlex<sup>®</sup> supply interruption that occurred in mid-June 2013. Restated for the Increlex<sup>®</sup> supply interruption, sales were up 13.8% year-on-year, driven by the solid volume and value growth of Somatuline<sup>®</sup>, and by the solid performance of Dysport<sup>®</sup> in therapeutics and aesthetics through the product supply to Valeant. Sales in North America represented 4.7% of consolidated Group sales, compared to 5.6% a year earlier.

Sales generated in the **Rest of the World** reached €80.8 million, up 6.1% year-on-year. Performance was affected by a non-recurring effect in Vietnam, where orders had been anticipated in the first quarter 2013 before the expiry of import licenses for certain primary care products. Restated for this effect, sales were up 8.5%, driven by strong volume growth in China (notably Decapeptyl<sup>®</sup> and Smecta<sup>®</sup>), the Middle East and Brazil where Dysport<sup>®</sup> sales recorded good performance in aesthetics and therapeutics. In the first quarter 2014, sales in the Rest of the World accounted for 26.4% of total consolidated Group sales, compared to 26.1% the previous year.

<sup>2</sup> In accordance with the norm IFRS11 « Partnerships » applicable since 1<sup>st</sup> January 2014 on the accounting treatment of joint ventures

<sup>&</sup>lt;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 2013. 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 uro-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.ipsen.com.

# **Forward Looking Statement**

The forward-looking statements, objectives and targets contained herein are based on the Group's management strategy, current views and assumptions. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated herein. All of the above risks could affect the Group's future ability to achieve its financial targets, which were set assuming reasonable macroeconomic conditions based on the information available today. Use of the words "believes," "anticipates" and "expects" and similar expressions are intended to identify forward-looking statements, including the Group's expectations regarding future events, including regulatory filings and determinations. Moreover, the targets described in this document were prepared without taking into account external growth assumptions and potential future acquisitions, which may alter these parameters. These objectives are based on data and assumptions regarded as reasonable by the Group. These targets depend on conditions or facts likely to happen in the future, and not exclusively on historical data. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties, notably the fact that a promising product in early development phase or clinical trial may end up never being launched on the market or reaching its commercial targets, notably for regulatory or competition reasons. The Group must face or might face competition from generic products that might translate into a loss of market share. Furthermore, the Research and Development process involves several stages each of which involves the substantial risk that the Group may fail to achieve its objectives and be forced to abandon its efforts with regards to a product in which it has invested significant sums. Therefore, the Group cannot be certain that 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**

#### **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 (<a href="https://www.ipsen.com">www.ipsen.com</a>).

- 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® drug substance), is experiencing manufacturing issues with Increlex®. Supply interruption occurred in mid-June 2013 in the US and in Q3 2013 in Europe and the rest of the world. On December 18<sup>th</sup> 2013, Ipsen announced that Lonza had successfully re-manufactured the active ingredient of Increlex® and that the European Medicines Agency (EMA) had been informed that Ipsen was preparing for the resupply of Increlex® in the European Union. Consultations with the National competent authorities have allowed a resupply in Europe early 2014. Resupply in the US is still pending. Ipsen is actively working with its third party manufacturer and the Food and Drug Administration (FDA) to bring Increlex® back to the US market 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 the first quarter 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® Depot® (lanreotide) 120 mg Injection (« Somatuline® ») 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® phase III clinical study evaluating the antiproliferative effect of Somatuline® 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 million¹. 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® in NETs in the first half of 2014. Maximum incremental annual cost associated with the launch of Somatuline® in the NET indication in the US is expected to range from €30 million to €40 million. As a result, US breakeven², 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) during the 16-week double-blind phase of the study. 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® 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 World³ (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®, DNG did not demonstrate the statistical non-inferiority in

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

<sup>&</sup>lt;sup>2</sup> Commercial contribution excluding Increlex<sup>®</sup> (mecasermin [rDNA origin]) Injection sales and revenues from U.S. collaboration with Valeant Pharmaceuticals Intl Inc. in aesthetic medicine

<sup>&</sup>lt;sup>3</sup> Latin America, Middle East and Asia (ex Japan and China)



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>1</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 single dose. Across the studies, DNG showed safety profiles consistent with the known safety profile of Dysport<sup>®</sup>. 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>2</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% from c.30%. Mayroy's stake in Ipsen's share capital and voting rights now amounts to c.57.6% and c.73.3% 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 June 30, 2015.

<sup>2</sup> Latin America, Middle East and Asia (ex Japan and China)

<sup>&</sup>lt;sup>1</sup> Truong D. et al. Mov. Disord., 2005; 20 (7) 783-791; Truong et al., Parkinsonism Relat Disord. 2010 Jun;16(5):316-23

<sup>&</sup>lt;sup>3</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



### After 31 March 2014, major developments included:

- 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<sup>®</sup> 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<sup>®</sup> injection, the Phase III clinical study results demonstrated that:
  - Patients treated with Dysport<sup>®</sup> showed a statistically significantly (p<0.0001) higher proportion of responders in muscle tone improvement versus placebo (i.e. exhibiting ≥1 point improvement as measured by the Modified Ashworth Scale, MAS). At week 4, patients treated with Dysport<sup>®</sup> 500 units and 1000 units showed responding rates of 73.8% and 78.5%, respectively, compared to 22.8% in the placebo arm;
  - 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 ≥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.



#### **Government measures**

In the current context of financial and economic crisis, the governments of many countries in which the Group operates continue to introduce new measures to reduce public health expenses, some of which have affected the Group sales and profitability in the first quarter 2014. In addition, certain measures introduced in 2013 have continued to affect the Group's accounts year-on-year.

# Measures impacting the first quarter 2014:

# In the Major Western European countries:

- In France, health authorities have required price cuts of 5.5% on NutropinAq<sup>®</sup> in June 2013, of 12.5% on Nisis<sup>®</sup>/Nisisco<sup>®</sup> in October 2013, of 7.5% on Smecta<sup>®</sup> as of 1<sup>st</sup> January 2014 (a second cut of the same magnitude will apply as of 1<sup>st</sup> July 2014), of 6.5% on Fortrans<sup>®</sup> as of 1<sup>st</sup> January 2014 and of 4.0% on Decapeptyl<sup>®</sup> as of 1<sup>st</sup> April 2014. Moreover, Hexvix<sup>®</sup> has once again been reimbursed on the list "en sus" since December 2013;
- In the UK, the new PPRS (*Pharmaceutical Price Regulation Scheme*) was implemented, with the option for pharmaceutical companies to apply a price cut on the NHS (*National Health Service*) selling price of 5.0% to 7.0%, modulated on the whole portfolio, or to repay this amount through pay back. Moreover, since January 2014, tenders are managed at the regional level instead of the hospital level;
- 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, a first draft of the Royal Decree was published by the Ministry of Health in March 2014 announcing the implementation of an international price reference system based on the lowest price per mg in the 28 countries of the European Union. The application, which could occur in June 2014, will affect all LhRH (Luteinizing hormone-Releasing Hormone) analogues, including Decapeptyl<sup>®</sup>. Moreover, prices negotiated with hospitals during tenders will potentially be published and the official price would be aligned on the lowest price negotiated;
- In Italy, Hexvix® obtained reimbursement at the national level, and as a result, experienced a 13.0% official price cut in February 2014.

# In the Other European countries:

- In Belgium, a modulated price decrease of 1.95% on reimbursed products has been applicable since the implementation of the Inami tax on 1<sup>st</sup> April 2013;
- In the Netherlands, the NZA (Dutch health authority) transferred the budget for Growth Hormones from retail to hospital and introduced a new reimbursement system on 1<sup>st</sup> January 2013. The publication of the list containing the next wave of drugs to move to hospital budget was officially delayed. The application of international reference pricing led to price decreases 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;
- In Finland, a general price cut of 5.0% was applied on all drugs as of 1<sup>st</sup> February 2013;
- In Sweden, since January 2014, products that have been marketed for more than 15 years (i.e. Decapeptyl®) are subject to a mandatory price cut of 7.5%;
- 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 Portugal, new measures published in 2013 call for a 6.0% price cut on all drugs and for a contribution of the pharmaceutical industry to the decrease of healthcare spending through the setup, by every pharmaceutical company, of a provision fund equal to 2.0% of sales;
- In Greece, a new price revision impacting the majority of specialty care products commercialized by Ipsen occurred in February 2014. Decapeptyl<sup>®</sup> is not concerned by the price cuts but patient copayment increased significantly. Finally, since 1<sup>st</sup> April 2014, the Ministry of Health 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 Latvia, a national tender for LhRH analogues was put in place by local authorities in order to avoid parallel trades. A new reference basket was set up in July 2013. Initially, the basket was composed of all members of the European Union but now comprises Lithuania, Estonia, Czech Republic, Slovakia, Romania, Hungary, and Denmark. The reference pricing rule remains unchanged and calls for taking the 3<sup>rd</sup> lowest price of the basket;
- In Estonia, the price of Decapeptyl® 1M was reduced after implementation of the international reference price;
- In Czech Republic, the VAT on drugs has increased from 14.0% to 15.0% in January 2013. New
  prices were published on 1<sup>st</sup> January 2013. They stem from the international reference pricing
  system (average of the 3 lowest prices in 18 countries of the European Union). Moreover, since
  January 2013, Growth Hormones are no longer considered a hospital product and hence subject to
  price revisions;
- In Slovakia, new prices were published on 1<sup>st</sup> June 2013. They were the result of the international reference pricing system based on the average of the 3 lowest prices prevailing in the 28 countries of the European Union. A new price revision associated with the international reference price is ongoing with a publication anticipated in October 2014;
- In Poland, a new reimbursement limit was set after the launch of a competing product to Decapeptyl<sup>®</sup>. It led to the introduction of patient co-payments as of 1<sup>st</sup> January 2013 and, thereafter, to a general price decrease by the industry as a way of compensating. A price revision has been applicable since 1<sup>st</sup> January 2014 affecting Decapeptyl<sup>®</sup> and Somatuline<sup>®</sup>;
- In Romania, whereas prices are generally revised annually in March, the Ministry of Health has decided to maintain a price freeze until the final methodology for determining prices has been validated;
- In Switzerland, Dysport® was impacted by a price cut in December 2013 following the application of the international reference price (which takes place every three years).

### In the Rest of the World:

- In China, the willingness to implement an international reference pricing system, announced in 2012, has not advanced because authorities are prioritizing price control of products included on the Essential Drug List (EDL). In this context, Tanakan®, which is included on the "low price product" list about 80% of the EDL might experience a 10.0% cut on its hospital bidding price. The bidding price being identical to that invoiced to patients, the government has committed to compensate hospitals using these low price products;
- 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 that of Dysport<sup>®</sup>. In August 2013, the prices of 195 medicines had already been regulated, including that of Somatuline<sup>®</sup>;
- In Ukraine, authorities introduced a 7.0% VAT on drugs as of 1<sup>st</sup> April 2014 as part of an "anti-crisis" law. The measure, which was announced and voted within a couple of days, triggered a sudden stop in the availability of certain drugs in the country. Moreover, in terms of referencing, there are discussions to expand the current basket of reference countries (Bulgaria, Moldavia, Poland, Czech Republic, Slovakia) to three other countries (Latvia, Hungary and Serbia) on certain classes of drugs as a pilot scheme;

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 2014 and beyond

## In the Major Western European countries:

• In France, the social security budget act for 2014 (PLFSS) introduced, for the first time, the possibility for the pharmacist to substitute biotechnology products by biosimilars, except when the physician forbids it on the prescription. This rule has not yet been enacted and must be subject to a decree. It could potentially have an impact on NutropinAq®.

# In the Other European countries:

- 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 is thinking of introducing an extraordinary tax with a particular attention to pharmaceutical industry profits. Moreover, the new 3.0% tax on all hospital business announced late 2013, to become effective in 2014, has not been introduced;
- In Greece, the €2.44 billion claw-back as of end 2013 has not been readjusted by the Ministry of Health as initially anticipated. Health authorities are aiming at €2 billion for 2014;
- In Croatia, Czech Republic replaced France in the basket of countries included in the international reference pricing system;
- In Serbia, as of 1<sup>st</sup> July 2013, the Ministry of Health decided to include Romania in the basket of countries used for the calculation of international reference pricing. The rule is to take the average of the prices prevailing in Croatia, Slovenia, Italy and Romania;
- In Slovakia, as of 1<sup>st</sup> March 2014, a price decrease based on the average of the 3 lowest prices in the 28 countries of the European Union will apply to several Ipsen products.

### In the Rest of the World:

- In Algeria, Ipsen had to renew the Marketing Authorizations for all its Primary Care products before the end of 2013. This process could lead to price revisions in the first semester of 2014. Moreover, the list of reference prices edited in October 2013 has not yet triggered price decreases. The risk lays on Decapeptyl®, which price is likely to be aligned with the least expensive molecule;
- In Morocco, government announced reductions of the public and hospital prices of about 5,000 products belonging to different classes (hypertension, anti-infective agents, migraine, etc.) in January 2014. Although the impact on public prices was limited (1.0%), the measure affected the hospital sector with average decreases of 5.0% to 6.0%. This situation penalizes all pharmaceutical companies, notably foreign ones, in a country where overall margins are already low;
- In China, regulatory authorities are strongly encouraging innovations regarding the management of the Essential Drug List. As such, in February 2014, the Guangdong province (110 million inhabitants) pioneered in the launch of an online province-wide tender platform. An average price decrease of 9.0% was reported for products competing in the tenders;
- Turkey is thinking of introducing a flexible price system in 2014. The exact content is not yet known
  but measures such as not including countries under Troïka (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
  considered:
- In Brazil, products with no generics on the market will benefit from a 1% price increase in 2014.



# Comparison of consolidated sales for the first quarters of 2014 and 2013

### Sales by geographical area

Note: Unless stated otherwise, all variations in sales are stated excluding foreign exchange impacts by restating the Q1 2013 sales with the Q1 2014 exchange rates.

Group sales by geographical area in the first quarters of 2014 and 2013 were as follows:

(in million euros)		
	_	
	France	
Uni	ted Kingdom	
	Spain	
	Germany	
	Italy	
Major Western European countries		
Eas	stern Europe	
Of	thers Europe	
Other European Countries		
North America		
	Asia	
Other countries in the rest	t of the world	
Rest of the World		
Group Sales		
Of which: Total Drug Sales		
Drug-related Sales *		

i Quarter				
2014	2013	% Change	% Change at constant currency	
54.3	58.6	-7.3%	-7.3%	
13.8	13.2	4.9%	1.9%	
14.6	14.4	1.2%	1.2%	
24.3	20.5	18.5%	18.5%	
22.2	20.9	6.3%	6.3%	
129.3	127.6	1.3%	1.0%	
44.2	46.0	-3.8%	4.0%	
37.4	35.8	4.5%	5.1%	
81.6	81.7	-0.2%	4.5%	
14.3	17.3	-17.0%	-14.0%	
40.3	39.4	2.4%	4.4%	
40.5	40.7	-0.6%	7.8%	
80.8	80.1	0.9%	6.1%	
305.9	306.6	-0.2%	2.4%	
301.9	297.3	1.5%	4.3%	
4.1	9.3	-56.3%	-56.4%	

1<sup>st</sup> Quarter

In the first quarter 2014, sales generated in the **Major Western European countries** amounted to €129.3 million, up 1.0% year-on-year. The dynamic growth of specialty care products was partially offset by the decline of French primary care sales. Sales in the Major Western European countries represented 42.2% of total Group sales in the first quarter 2014, compared to 41.6% the previous year.

France – In the first quarter 2014, sales reached €54.3 million, down 7.3% year-on-year, affected by the decline of primary care sales. Sales of Smecta® decreased over the period, penalized by the 7.5% price decrease applied as of 1st January 2014 and a lower level of gastroenteritis epidemic than last year. Sales of Tanakan® were impacted by an unfavorable comparison base associated with the launch of a second "me-too" product in March 2013, while sales of Forlax® suffered from generics competition. Sales of specialty care products, stable over the period, were driven by the sustained growth of Somatuline® and NutropinAq® sales, offset by the decrease in Decapeptyl® sales, notably associated with inventory reductions in anticipation of a price decrease applied as of 1st April 2014. Consequently, the relative weight of France in the Group's consolidated sales has continued to decrease and now represents 17.8% of total Group sales, compared to 19.1% the previous year.

**United Kingdom** – In the first quarter 2014, sales reached €13.8 million, up 1.9% year-on-year, fueled by the volume growth of Somatuline<sup>®</sup>, which market share increased six points since September 2013, and of Decapeptyl<sup>®</sup>. In the first quarter 2014, the United Kingdom represented 4.5% of total Group sales, compared to 4.3% the previous year.

Active ingredients and raw materials



**Spain** – In the first quarter 2014, sales reached €14.6 million, up 1.2% year-on-year, driven by the robust growth of Somatuline<sup>®</sup> sales. In the first quarter 2014, sales in Spain represented 4.8% of total Group sales, compared to 4.7% the previous year.

Germany – In the first quarter 2014, sales reached €24.3 million, up 18.5% year-on-year, driven by strong volume growth of Somatuline® and Hexvix®. Growth benefited from the favorable impact associated with the reduction (from 16% to 7%) in mandatory rebates on prescription drug sales. Restated from this element, sales grew 10.1%. Over the period, sales in Germany represented 7.9% of total Group sales, compared to 6.7% a year earlier.

Italy – In the first quarter 2014, sales reached €22.2 million, up 6.3% year-on-year, marked by the strong growth of Somatuline® and by a favorable effect arising from a change in the distribution model of Forlax®. Indeed, the affiliate had recorded no Forlax® sales in the first quarter 2013 due to this change in distribution model. Restated for this base effect, sales were up 3.0%. In the first quarter 2014, sales in Italy represented 7.3% of total Group sales, compared to 6.8% the previous year.

In the first quarter 2014, sales generated in the **Other European countries** reached €81.6 million, up 4.5% year-on-year, penalized 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 accounting¹. Restated for this base effect, sales were up 10.2%. Moreover, sales were driven by solid volume growth in Russia, where Dysport® continues to penetrate the aesthetics and therapeutics markets and where Tanakan® records strong growth, the supply of Dysport® for aesthetic use to Galderma, and the solid performance of the Netherlands and the Czech Republic. Sales were penalized by the consequences of the political crisis ongoing in Ukraine. In the first quarter 2014, sales in this region represented 26.7% of consolidated Group sales, a stable ratio year-on-year.

In the first quarter 2014, sales generated in **North America** reached €14.3 million, down 14.0% year-on-year, mainly impacted by the Increlex<sup>®</sup> supply interruption that occurred in mid-June 2013. Restated for the Increlex<sup>®</sup> supply interruption, sales were up 13.8% year-on-year, driven by the solid volume and value growth of Somatuline<sup>®</sup>, and by the solid performance of Dysport<sup>®</sup> in therapeutics and aesthetics through the product supply to Valeant. Sales in North America represented 4.7% of consolidated Group sales, compared to 5.6% a year earlier.

In the first quarter 2014, sales generated in the **Rest of the World** reached €80.8 million, up 6.1% year-on-year. Performance was affected by a non-recurring effect in Vietnam, where orders had been anticipated in the first quarter 2013 before the expiry of import licenses for certain primary care products. Restated for this effect, sales were up 8.5%, driven by strong volume growth in China (notably Decapeptyl<sup>®</sup> and Smecta<sup>®</sup>), the Middle East and Brazil where Dysport<sup>®</sup> sales recorded good performance in aesthetics and therapeutics. In the first quarter 2014, sales in the Rest of the World accounted for 26.4% of total consolidated Group sales, compared to 26.1% the previous year.

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<sup>&</sup>lt;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



#### Sales by therapeutic area and by product

The following table shows sales by therapeutic area and by product for the first quarters of 2014 and 2013:

1<sup>st</sup> Quarter

(in million euros)		
Uro-oncology		
O10-o11cology	of which Hexvix®	
	of which Decapeptyl®	
Endocrinology	or which becapeptyr	
Litationiogy	of which Somatuline®	
	of which NutropinAq®	
	of which Increlex®	
Neurology	or which morelex	
	of which Dysport®	
Specialty Care	, , , , , , , , , , , , , , , , , , ,	
Gastroenterology		
	of which Smecta®	
	of which Forlax®	
Cognitive Disorders		
	of which Tanakan®	
Cardiovascular		
0	f which Nisis <sup>®</sup> & Nisisco <sup>®</sup>	
	of which Ginkor®	
Other Primary Care		
	of which Adrovance®	
Primary Care		
Total Drug Sales		
Drug-related Sales*		
Group Sales		
	, motoriala	

2014	2013	% Change	% Change at constant currency	
78.2	74.3	5.4%	6.1%	
4.4	4.0	11.0%	10.5%	
73.8	70.2	5.0%	5.9%	
86.2	81.9	5.4%	6.9%	
68.5	61.5	11.3%	13.0%	
15.8	14.1	12.4%	13.0%	
2.0	6.3	-68.6%	-67.8%	
60.8	60.8	-0.1%	6.3%	
60.8	60.8	-0.1%	6.3%	
225.3	217.0	3.8%	6.4%	
51.9	53.7	-3.3%	-0.8%	
30.2	29.7	2.0%	4.1%	
8.4	8.9	-5.7%	-4.9%	
16.3	17.4	-6.6%	-0.4%	
16.3	17.4	-6.6%	-0.4%	
5.5	6.2	-10.8%	-10.4%	
1.7	2.0	-12.3%	-12.3%	
3.6	4.2	-14.1%	-13.6%	
2.9	3.1	-6.2%	-5.9%	
2.3	2.6	-10.3%	-10.3%	
76.6	80.4	-4,7%	-1.7%	
301.9	297.3	1.5%	4.3%	
4.1	9.3	-56.3%	-56.4%	
305.9	306.6	-0.2%	2.4%	

In the first quarter 2014, sales of **Specialty Care products** reached €225.3 million, up 6.4% year-on-year. Sales in Uro-oncology, Endocrinology, and Neurology grew by respectively 6.1%, 6.9% and 6.3% year-on-year. In the first quarter 2014, the relative weight of specialty care products continued to increase to reach 73.6% of total Group sales, compared to 70.8% the previous year.

In Uro-oncology, sales of Decapeptyl® reached €73.8 million in the first quarter 2014, up 5.9% year-on-year. This performance took place in the context of a strained environment in Europe, negatively impacted by a contracting pharmaceutical market, more frequent use of co-payment in Southern Europe and a slowdown in the growth of Eastern European countries. Sales in Ukraine were penalized by the ongoing political situation. Moreover, sales in France suffered from inventory reductions in anticipation of the 4.0% price decrease applied as of 1<sup>st</sup> April 2014. In China, double-digit growth resumed in the first quarter 2014 after a year 2013 affected by a strained competitive environment and the disruption of hospital market promotion. In addition, sales in the Middle East posted solid growth. In the first quarter 2014, sales of Hexvix® amounted to €4.4 million, mostly generated in Germany. Over the period, sales in Uro-oncology represented 25.6% of total Group sales, compared to 24.2% the previous year.

<sup>\*</sup> Active ingredients and raw materials



In **Endocrinology**, sales continued to progress to reach €86.2 million in the first quarter 2014, up 6.9% year-on-year, representing 28.2% of total Group sales, compared to 26.7% the previous year.

**Somatuline**<sup>®</sup> – In the first quarter 2014, sales reached €68.5 million, up 13.0% year-on-year, driven by strong volume and value growth in the United States and by a solid performance in Germany, where strong volume growth was accompanied by a reduction (from 16% to 7%) in mandatory rebates on prescription drug sales. The product also recorded positive momentum in the Netherlands, Italy and Denmark.

**NutropinAq**<sup>®</sup> – In the first quarter 2014, sales reached €15.8 million, up 13.0%, driven by good performance in Germany, France and Italy.

**Increlex**<sup>®</sup> – In the first quarter 2014, sales reached €2.0 million, down 67.8%, affected by the shortage situation outstanding since mid-June 2013 in the United States and since August 2013 in Europe. Supply resumed in Europe in early 2014.

In **Neurology**, **Dysport**<sup>®</sup> sales reached €60.8 million in the first quarter 2014, up 6.3% year-on-year. Growth was mainly driven by the supply of Dysport<sup>®</sup> for aesthetic use to Galderma and by solid performance in Brazil and Russia for both the therapeutics and aesthetics segments. Growth was affected by the consequences of the political crisis in Ukraine. Dysport<sup>®</sup> sales represented 19.9% of total Group sales, a stable ratio year-on-year.

In the first quarter 2014, sales of **Primary Care** products amounted to €76.6 million, down 1.7% year-on-year. Sales recorded solid performance in China, Russia, and Algeria. Sales in France declined by 15.3% year-on-year, affected by the launch of a competitive product to Tanakan<sup>®</sup> in March 2013, the 7.5% price cut on Smecta<sup>®</sup> implemented as of 1<sup>st</sup> January 2014, and the negative consequences arising from the reinforcement of the "Tiers-Payant<sup>1</sup>" regulation. In the first quarter 2014, primary care sales represented 25.0% of Group consolidated sales, compared to 26.2% the previous year. Primary care sales in France accounted for 31.1% of the Group's total primary care sales, compared to 35.0% the previous year.

In **Gastroenterology**, sales reached €51.9 million, down 0.8% year-on-year, penalized by a strong first quarter 2013, when orders had been anticipated before the expiry of import licenses for certain primary care products.

Smecta® – In the first quarter 2014, sales reached €30.2 million, up 4.1% year-on-year, driven by strong growth in China and Algeria, partially offset by the performance in France, affected by a low level of gastroenteritis epidemic and the 7.5% price cut implemented as of 1<sup>st</sup> January 2014. Smecta® sales represented 9.9% of total Group sales over the period, compared to 9.7% the previous year.

**Forlax**<sup>®</sup> – In the first quarter 2014, sales reached €8.4 million, down 4.9% year-on-year, mainly affected by the reinforcement of the "Tiers-Payant¹" regulation in France. In the first quarter 2014, France represented 46.7% of total product sales, compared to 60.8% the previous year.

In the **cognitive disorders area**, sales of **Tanakan**<sup>®</sup> in the first quarter 2014 reached €16.3 million euros, down 0.4% year-on-year, penalized by the launch of a second "me-too" product in France in March 2013 and by a change in the commercial model for Spain, where the product is now distributed by a partner. The product recorded good performance in Russia. In the first quarter 2014, 24.1% of Tanakan<sup>®</sup> sales were achieved in France, compared to 25.9% the previous year.

In the cardiovascular area, sales amounted to €5.5 million euros in the first quarter 2014, down 10.4% year-on-year, mainly impacted by the decline of Nisis® / Nisisco® and Ginkor Fort® sales.

Sales of **Other primary care products** reached €2.9 million in the first quarter 2014, down 5.9% year-on-year, mainly impacted by the 10.3% decline in **Adrovance**<sup>®</sup> sales.

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



In the first quarter 2014, **drug-related sales (active ingredients and raw materials)** reached €4.1 million, down 56.4% year-on-year. Performance was penalized 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>1</sup>. Restated for this base effect, sales were down 23.2%.

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<sup>&</sup>lt;sup>1</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