PRESS RELEASE

# Ipsen's first quarter 2013 sales

- **Group sales up 5.3%[1]**
- **Solid specialty care growth, up 8.0%[1]**
  - Somatuline® up 12.6%[1]
  - Dysport® up 8.4%[1]
- **Resilience of Primary care, down 1.9%[1], supported by strong international sales growth**
- **2013 Group financial objectives reiterated**

**Paris (France), 25 April 2013 -** Ipsen (Euronext: IPN; ADR: IPSEY) reported today its sales for the first quarter 2013.

**First quarter 2013 unaudited IFRS consolidated sales**

| *(in million euros)* | ***2013*** | ***2012*** | *% Change* | *% Change at constant currency* |
|---|---|---|---|---|
| **SALES BY REGION** | | | | |
| Major Western European countries | 127.6 | 135.6 | (5.9%) | (5.7%) |
| Other European countries | 81.7 | 77.0 | 6.1% | 6.2% |
| North America | 17.3 | 16.4 | 5.2% | 6.6% |
| Rest of the world | 80.1 | 63.8 | 25.5% | 27.6% |
| **Group Sales** | **306.6** | **292.8** | **4.7%** | **5.3%** |
| **SALES BY THERAPEUTIC AREA** | | | | |
| Specialty care | 217.0 | 202.4 | 7.2% | 8.0% |
| Primary care | 80.4 | 81.9 | (1.9%) | (1.9%) |
| **Total Drug Sales** | **297.3** | **284.4** | **4.6%** | **5.1%** |
| **Drug-related sales[2]** | 9.3 | 8.4 | 10.7% | 11.5% |
| **Group Sales** | **306.6** | **292.8** | **4.7%** | **5.3%** |

Commenting on the first quarter 2013 performance, **Marc de Garidel, Chairman and Chief Executive Officer of Ipsen** said: "*Ipsen is off to a good start this year with a solid specialty care growth, up 8.0%, notably driven by the good performance of Somatuline®. Moreover, primary care proved resilient with strong growth of Smecta® sales and international sales.*" **Marc de Garidel** added : *"Despite supply shortage issues with Increlex®, Ipsen confirms its 2013 guidance, both in terms of sales and recurring adjusted[3] operating margin."*

[1] Year-on-year growth excluding foreign exchange impacts
[2] Drug related sales correspond to sales of active indredients and raw materials
[3] Before non-recurring elements

## First quarter 2013 sales highlights

**Consolidated Group sales** reached €306.6 million in the first quarter 2013, up 5.3% year-on-year excluding foreign exchange impacts[1].

**Drug sales** reached €297.3 million in the first quarter 2013, up 5.1% year-on-year excluding foreign exchange impacts[1], driven by solid **Specialty Care** growth, up 8.0% year-on-year excluding foreign exchange impacts[1]. Endocrinology, neurology and uro-oncology sales grew year-on-year by 10.8%, 8.4% and 4.7%, respectively, excluding foreign exchange impacts[1]. In the first quarter 2013, the relative weight of specialty care products continued to increase to reach 70.8% of total Group sales, compared to 69.1% the previous year.

Sales of **Primary Care products** amounted to €80.4 million, down 1.9% year-on-year excluding foreign exchange impacts[1], negatively impacted in France by the consequences of a tougher competitive environment and by the step-up during the summer 2012 of the regulation known as "Tiers-Payant[2]", partly offset by strong international sales growth.

Sales in the **Major Western European countries** amounted to €127.6 million, down 5.7% year-on-year excluding foreign exchange impacts[1]. The dynamic specialty care volume growth was more than offset by:

- In France, the consequences of a tougher primary care competitive environment and the slight decline in specialty care sales, mainly due to the collateral effect of the restructuring plan;
- In Spain, the significant decline of the Spanish pharmaceutical market which negatively impacted Decapeptyl® sales.

Sales in **Other European countries** reached €81.7 million, up 6.2% year-on-year excluding foreign exchange impacts[1]. Sales growth was mainly driven by Russia where both specialty care (notably Dysport® and Decapeptyl®) and primary care (notably Tanakan® and Fortrans®) performed strongly. In the first quarter 2013, sales in this region represented 26.7% of total consolidated Group sales compared to 26.3% the previous year.

Sales in **North America** reached €17.3 million, up 6.6% year-on-year excluding foreign exchange impacts[1], mainly driven by the continuous penetration of Somatuline® in acromegaly, the supply of Dysport® for aesthetic use to Medicis and the growth of Dysport® in the treatment of cervical dystonia. Sales were negatively impacted by lower sales of Increlex® further to the management of the anticipated shortage period. Sales in North America represented 5.6% of total consolidated Group sales, a stable ratio year-on-year.

Sales generated in the **Rest of the World** reached €80.1 million, up 27.6% year-on-year excluding foreign exchange impacts[1]. This performance was mainly driven by strong volume growth in China (notably Decapeptyl®), in Australia (where the Group signed an agreement in April 2012 with Galderma for the distribution of Dysport® in aesthetic use), in Algeria and in Vietnam. Sales in the Rest of the World reached 26.1% of total consolidated Group sales in the first quarter 2013 compared to 21.8% the previous year.

[1] Variations excluding foreign exchange impacts are computed by restating the first three months of 2012 with the first three months of 2013 average exchange rates

[2] « Tiers-Payant » regulation: the patient now pays upfront for a branded drug and is later reimbursed

## About Ipsen

Ipsen is a global specialty-driven pharmaceutical company with total sales exceeding €1.2 billion in 2012. 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 2012, R&D expenditure totalled close to €250 million, representing more than 20% of Group sales. The Group has close to 4,900 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.

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 Generics 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. 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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**APPENDICES**

## 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 2012 Registration Document available on its website www.ipsen.com

- The Group is dependent on the setting of prices for medicines and is vulnerable to the possible reduction of prices of certain of its products by public or private payers or to their possible withdrawal from the list of reimbursable products by the relevant regulatory authorities in the countries where it does business. In general terms, 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 private 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 generate or may generate substantial royalties for the Group, but these third parties could behave in ways which 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 a 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 delay or 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, for example, Forlax® or Smecta® (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 to 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 in 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 it 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, Ipsen's supplier of Increlex® active ingredient, is facing manufacturing issues with Increlex® at its Hopkinton site (MA, USA). Lonza is working closely with the Food and Drug Administration (FDA) to address these issues. Ipsen is diligently addressing management of the shortage period to reduce its impact on the patients and their families. The supply interruption is expected in Q2 2013 in the US and in Q3 2013 in Europe and the rest of the world. Re-supply before the end of 2013 is not currently anticipated.

- In certain countries exposed to significant public deficits, and where it sells its drugs directly to public hospitals, the Group could face discount or lengthened payment terms or difficulties in recovering its receivables in full. In Greece notably, which represented in 2011 approximately 1.6% of consolidated sales, and where payment terms from public hospitals are particularly long, the Group is closely monitoring the current situation. 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. Ipsen Pharmaceuticals, Inc. has received an administrative demand from the United States Attorney's Office for the Northern District of Georgia seeking documents relating to its sales and marketing of Dysport® (abobotulinumtoxinA) for therapeutic use. Ipsen's policy is to fully comply with all applicable laws, rules and regulations. Ipsen is cooperating with the U.S. Attorney's Office in responding to the government's administrative demand. Additionally, In February 2012, Allergan has commenced legal proceedings against Ipsen in Italy and in the United Kingdom concerning an alleged patent infringement. The patents claim certain therapeutic uses of botulinum toxin products in the field of urology. Ipsen will vigorously defend its rights in these legal proceedings, which are based on patents that are being challenged by Ipsen in opposition proceedings before the European Patent Office.

## MAJOR DEVELOPMENTS

During the first quarter 2013, major developments included:

- On January 17, 2013 – Teijin Pharma Limited, the core company of the Teijin Group's healthcare business, and Ipsen announced the launch of Somatuline® 60/90/120 mg for subcutaneous injection in Japan for the treatment of acromegaly and pituitary gigantism (when response to surgical therapies is not satisfactory or surgical therapies are difficult to perform). In Japan, Teijin Pharma holds the rights to develop and market the drug.
- On January 24, 2013 – Ipsen and Inspiration Biopharmaceuticals Inc. (Inspiration) today announced they entered into an Asset Purchase Agreement (APA) whereby Baxter International (Baxter) agrees to acquire the worldwide rights to OBI-1, a recombinant porcine factor VIII (rpFVIII) in development for congenital hemophilia A with inhibitors and acquired hemophilia A, and Ipsen's industrial facility in Milford (Boston, MA). The APA was filed on 23 January 2013, with the US Federal Bankruptcy Court in Boston (MA). The sale is a result of joint marketing and sale process pursued by Ipsen and Inspiration shortly after Inspiration filed for protection under Chapter 11 of the U.S. Bankruptcy Code on October 30, 2012. The APA is subject to certain closing conditions, including Bankruptcy Court and regulatory approvals. Ipsen has agreed to extend the DIP to Inspiration for a period of 45 days i.e. for an additional amount of up to c. $5 million.
- On 6 February 2013 - Ipsen and Inspiration Biopharmaceuticals Inc. (Inspiration) announced they entered into an Asset Purchase Agreement (APA) whereby Cangene Corporation (Cangene) agrees to acquire the worldwide rights to IB1001, a recombinant factor IX (rFIX) for the treatment of hemophilia B. Under the terms of the APA, Cangene has agreed to pay $5.9 million upfront, up to $50 million in potential additional commercial milestones as well net sales payments equivalent to tiered double digit percentage of IB1001 annual net sales. The APA is subject to certain closing conditions including Bankruptcy Court approval.
- On 7 February 2013 - Ipsen and Braintree Laboratories, Inc., a US-based company specializing in the development, manufacturing and marketing of specialty pharmaceuticals announced today that Eziclen® / Izinova® (BLI-800) successfully completed its European decentralized registration procedure involving sixteen countries. The product will be indicated in adults for bowel cleansing prior to any procedure requiring a clean bowel (e.g. bowel visualization including bowel endoscopy and radiology or surgical procedure).
- On 20 February 2013 - Ipsen and Inspiration Biopharmaceuticals Inc. (Inspiration) announced the closing of the sale of the proprietary hemophilia B product, IB1001 (recombinant FIX), to Cangene Corporation (Cangene). Ipsen and Inspiration jointly agreed to sell their respective commercialization rights to IB1001 as part of the transaction. Cangene acquired worldwide rights to IB1001, a recombinant factor IX currently under regulatory review in the United States and Europe.
- On 21 March 2013 - Ipsen and Inspiration Biopharmaceuticals Inc. (Inspiration) announced the closing of the sale of its lead hemophilia program, OBI-1 to Baxter International Inc. (Baxter), the global leader in hemophilia. Baxter acquired worldwide rights to OBI-1, a recombinant porcine factor VIII in development for the treatment of congenital hemophilia A with inhibitors and acquired hemophilia A, as well as Ipsen's manufacturing facility for OBI-1 in Milford, Massachusetts. The Ipsen employees working on the development and manufacturing of OBI-1 are offered employment by Baxter. Baxter has agreed to pay $50 million upfront, up to $135 million in potential additional development and sales milestones as well as tiered net sales payments ranging from 12.5% to 17.5% of OBI-1 global net sales. OBI-1 is currently in a pivotal trial for the treatment of individuals with acquired hemophilia A. As Inspiration's only senior secured creditor and as the owner of non-Inspiration assets that will be included in the sale of both OBI-1 and IB1001, Ipsen will receive at least 60% of the upfront payments. Over and above these upfront amounts, Ipsen will receive 80% of all payments up to a present value of $304 million and 50% of all proceeds thereafter.

After 31 March 2013, major developments included:

- On 9 April, 2013 –Ipsen announced that Health Canada has granted a marketing authorization for Dysport® (Botulinum toxin type A for injection) for the temporary improvement in the appearance of moderate to severe frown lines (glabellar lines) in adult patients younger than 65 years of age.

Medicis Aesthetics Canada, a division of Valeant Pharmaceuticals, will market Dysport® for use in aesthetic medicine in Canada. Launch is expected in April 2013.

- On 10 April, 2013 –PeptiDream Inc., a Tokyo-based pharmaceutical company (PeptiDream), and Ipsen announced that they have entered into a research collaboration and license option agreement to discover, evaluate, potentially develop and launch therapeutic peptides to treat serious medical conditions in areas of therapeutic focus for Ipsen.
- On 24 avril 2013 – Upon proposal of the Appointments and Governance Committee, the Board of Directors of Ipsen will propose to the Combined Shareholders' Meeting to be held on 31 May 2013 the renewal of the terms of office as Directors of Mr. Antoine Flochel and Mr. Gérard Hauser and the appointment as a Director of Mrs. Martha Crawford in replacement of Mr. Klaus-Peter Schwabe who did not request the renewal of his term of office.
- On 25 April, 2013 – Ipsen announced that the supplier of Increlex®'s (mecasermin [rDNA origin] Injection) active ingredient, Lonza, is facing manufacturing issues with Increlex® at its Hopkinton site (MA, USA). Lonza is working closely with the Food and Drug Administration (FDA) to address these issues. Ipsen is diligently addressing management of the shortage period to reduce its impact on the patients and their families. The supply interruption is expected in Q2 2013 in the US and in Q3 2013 in Europe and the rest of the world. Re-supply before the end of 2013 is not currently anticipated.
- On 25 April, 2013 – Active Biotech and Ipsen announced that the companies have updated the analysis plan for the 10TASQ10 trial, a global Phase III clinical trial evaluating tasquinimod in patients with metastatic castrate-resistant prostate cancer (mCRPC) who have not yet received chemotherapy. The companies now plan to conduct the primary PFS analysis for the 10TASQ10 trial in 2014, at the same time as the first interim overall survival (OS) analysis. The time point for the OS interim analysis will be driven by the number of OS events. The specified number of radiographic progression-free survival (PFS) events for the primary end-point will have been exceeded at the time of interim OS analysis.

## ADMINISTRATIVE MEASURES

In a 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 are affecting the Group sales and profitability in 2013. In addition, certain measures introduced in 2012 have continued to affect the Group's accounts year-on-year.

### Measures impacting 2013

**In the Major Western European countries:**

- In France, Tanakan® was delisted on 1st March 2012. An additional tax on promotional expenses of 0.6% has also been introduced. Moreover, sales of Nisis®/Nisisco® and Forlax® were negatively impacted by a step-up in July in the regulation known as “tiers-payant”, whereby the patient now pays upfront for a branded drug (when genericized) and is only reimbursed later on;
- In Spain, Tanakan® was dereimbursed on 1st September 2012. The new draft of the Royal Decree that establishes the new prices for products that are more than 10 years old was issued in March 2013 and affects all the LhRH analogues. Price impacts should be known during the 2nd quarter 2013;
- In Italy, the process of aligning on the lowest regional price for LhRH is not yet enforced. This due to the political context.

**In the Other European countries:**

- In Belgium, a modulated price decrease of 1.95% on reimbursed products is applicable since 1st April 2013 through the Inami tax;
- In Portugal, new countries have been included in the reference basket for the International Pricing System such as Slovakia, Spain and France. For retail products, the price is the average of the basket and, for hospital products, the price is the lowest price of the basket. The new prices have been enforced on 1st April 2013;
- In Hungary, a 10.0% additional tax on sales, on top of the 20.0% tax already in force, was introduced as of 1st August 2012 for all Somatuline® formulations;
- In Czech Republic, VAT on drugs was increased from 14% to 15% in January 2013. New prices have been published on 1st January 2013 as a result of International price referencing (average of the 3 lowest prices in EU 18), leading to price reductions in the range of -12% to -32% on Ipsen portfolio;
- In Slovakia, new prices have been published on 1st March 2013. It is the result of International reference pricing based on the 2nd lowest price in EU 27. The next price bulletin is already established but will be enforced on 1st June 2013 and is based on the average 3 lowest price in EU 27. Cumulative price decreases will impact Decapeptyl® by -6% and Somatuline® -7%;
- In Greece, a new price bulletin was been published mid February 2013, impacting all LhRH analogues;
- In Finland, a general price cut of 5% was applied on all drugs on 1st February 2013 on the basis of cost containement measures;
- In the Netherlands, switch of Growth Hormones budget from retail to hospital with new reimbursement system imposed by NZA (Dutch health authority) on 1st January 2013;
- In Poland, new limit of reimbursement was set by the launch of new competitor which led to patient co-payments on 1st January 2013 and thus to a general price decrease by the industry.

**In the Rest of the World:**

- China is still working on its international reference pricing system including ten countries such as the USA, France, Germany, South Korea and Japan;
- In January 2011, Algeria set reference pricing per therapeutic class, hence a price alignment of Decapeptyl® on the cheapest GnRH seems imminent; more recently, Algerian authorities have imposed a price decrease of 10% on Dysport® for the hospital market;
- In Korea, under the volume-control regulation in force since November 2011, the price of the 11.25 mg formulation of Diphereline® has been cut by 4.5% on 1st September 2012 and will be further cut in 2013 by 7.3%, while Dysport® price will be cut by 7%.

Furthermore, and in the context of 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 them will affect the Group sales and profitability beyond 2013. Health Technology Assessment (HTA) methods are more broadly used in market access decisions in several part of the world, including some emerging countries and Eastern European countries.

## Measures which may have impacts beyond 2013

**In the Major Western European countries:**

- In France, the taxable basis for the promotion tax has been significantly extended to the institutional communication and congresses by a decree published in December 2012;
- In Italy, the cap for hospital expenditure has been increased from 2.4% to 3.5%. In addition, Pharma Companies will have to pay 50.0% of any extra expenditure beyond this cap level.

**In the Other European countries:**

- In Portugal, the outcome of negotiations between Pharma industry and Ministry of Health on the reimbursement threshold borne by the industry is expected soon. The final 2012 reimbursment amount is not yet confirmed, nor is the 2013 threshold. The final agreement will be very much dependent on drug value expenditure to be reached in 2013 as percentage of GDP;
- In Greece, a new price bulletin is expected mid-year with further price adjustment. Claw-back will be adjusted, if any, by year-end, based on a €2.44 billion target set for 2013 by Ministry of Health. The government is aiming at €2 billion for 2014;
- In Belgium, International Reference Pricing was updated with new rules and a reference basket of 6 countries (France, Germany, the Netherlands, Austria, Ireland and Finland); it should be implemented in 2013;
- In the Netherlands, shift of budget for Somatostatin and LhRH analogues from retail to intra-mural hospital is expected in 2014;
- Within the frame of the Healthcare Reform, Russian Health Authorities are considering a possible change in the price-setting methodology for drugs on the Essential Drug List (EDL); future registered prices for drugs on the EDL should be set as the weighted average price of all drugs with the same International Non-proprietary Name (INN).

**In the Rest of the World:**

- In Colombia, a new International Reference pricing system was implemented during the second semester 2012, as well as maximum reimbursement prices on expensive drugs. Somatuline® could face a price cut in the range of 40%-50%;
- Twelve Latin American countries (Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, Guyana, Paraguay, Peru, Surinam, Uruguay, and Venezuela) agreed to create a regional drug-pricing database in order to harmonize drug prices. Launch and impacts are unknown at this stage.

## Comparison of consolidated sales for the first quarter 2013 and 2012:

### *Sales by geographical area*

Group sales by geographical area for the first quarter 2013 and 2012 were as follows:

| | First Quarter | | | |
|---|---|---|---|---|
| (in million euros) | 2013 | 2012 | % Variation | % Variation at constant currency |
| France | 58.6 | 68.4 | (14.4%) | (14.4%) |
| United Kingdom | 13.2 | 12.8 | 2.8% | 4.9% |
| Spain | 14.4 | 15.0 | (3.7%) | (3.7%) |
| Germany | 20.5 | 18.3 | 11.9% | 11.9% |
| Italy | 20.9 | 21.0 | (0.6%) | (0.6%) |
| **Major Western European countries** | **127.6** | **135.6** | **(5.9%)** | **(5.7%)** |
| Eastern Europe | 46.0 | 42.6 | 7.8% | 8.3% |
| Others Europe | 35.8 | 34.4 | 3.9% | 3.6% |
| **Other European Countries** | **81.7** | **77.0** | **6.1%** | **6.2%** |
| **North America** | **17.3** | **16.4** | **5.2%** | **6.6%** |
| Asia | 39.4 | 28.7 | 37.2% | 36.7% |
| Other countries in the rest of the world | 40.7 | 35.1 | 16.0% | 19.9% |
| **Rest of the World** | **80.1** | **63.8** | **25.5%** | **27.6%** |
| **Group Sales** | **306.6** | **292.8** | **4.7%** | **5.3%** |
| **Of which: Total Drug Sales** | **297.3** | **284.4** | **4.6%** | **5.1%** |
| **Drug-related Sales[1]** | **9.3** | **8.4** | **10.7%** | **11.5%** |

In the first quarter 2013, sales generated in the **Major Western European countries** amounted to €127.6 million, down 5.7% year-on-year excluding foreign exchange impacts[2]. The dynamic sales growth of specialty care products in volume was more than offset by the consequences of a tougher competitive environment in the French primary care market. Sales in the Major Western European countries represented 41.6% of total Group sales in the first quarter 2013, compared to 46.3% the previous year.

**France –** In the first quarter 2013, sales reached €58.6 million, down 14.4% year-on-year, penalized by the accelerating decline of primary care sales. The strong growth of Smecta®, resulting from a gastroenteritis epidemy larger than the previous year, was not sufficient to fully offset the decrease in primary care sales, driven by declining sales of Nisis®/Nisisco® (following the launch of several generics and a 15% price cut in November 2011) and of Tanakan® following the product delisting as of 1st March 2012. Additionally, since July 2012, sales of the Group's genericized drugs (Nisis®/Nisisco® and Forlax®) were negatively impacted by the step-up of the regulation known as "Tiers-Payant[3]". In the first quarter 2013, specialty care growth slightly declined, mainly due to the collateral effect of the restructuring plan, despite the solid volume growth of Somatuline® and NutropinAq®. Consequently, the relative weight of France in the Group consolidated sales continued to decrease, representing 19.1% of total Group sales compared to 23.4% in the previous year.

**United Kingdom –** In the first quarter 2013, sales reached €13.2 million, up 4.9% year-on-year excluding foreign exchange impacts[2], fuelled by Decapeptyl® and Somatuline® volume growth. In the first quarter 2013, the United Kingdom represented 4.3% of total Group sales compared to 4.4% the previous year.

[1] Active ingredients and raw materials
[2] Variations excluding foreign exchange impacts are computed by restating the first three months of 2012 with the first three months of 2013 average exchange rates
[3] « Tiers-Payant » regulation: the patient now pays upfront for a branded drug and is later reimbursed

**Spain –** In the first quarter 2013, sales reached €14.4 million, down 3.7% year-on-year, penalized by the significant decline of the Spanish pharmaceutical market which impacted Decapeptyl® sales. In the first quarter 2013, sales in Spain represented 4.7% of total Group sales compared to 5.1% the previous year.

**Germany –** In the first quarter 2013, sales reached €20.5 million, up 11.9% year-on-year, driven by the strong volume growth of Somatuline®, NutropinAq® and Dysport®. In the first quarter 2013, sales in Germany represented 6.7% of total Group sales compared to 6.2% the previous year.

**Italy –** In the first quarter 2013, sales reached €20.9 million, about stable year-on-year, negatively impacted by no Forlax® sales in the period resulting from a delay in the change of distribution model. The strong Decapeptyl® and Somatuline® volume growth almost offset the elements above. Italy represented 6.8% of the Group sales in the quarter compared to 7.2% the previous year.

In the first quarter 2013, sales generated in the **Other European countries** reached €81.7 million, up 6.2% year-on-year excluding foreign exchange impacts[1]. Sales growth was mainly driven by Russia where both specialty care (notably Dysport® and Decapeptyl®) and primary care (notably Tanakan® and Fortrans®) performed strongly. In the first quarter 2013, sales in this region represented 26.7% of total consolidated Group sales compared to 26.3% the previous year.

In the first quarter 2013, sales generated in **North America** reached €17.3 million, up 6.6% year-on-year excluding foreign exchange impacts[1], mainly driven by the continuous penetration of Somatuline® in acromegaly, the supply of Dysport® for aesthetic use to Medicis and the growth of Dysport® in the treatment of cervical dystonia. Sales were negatively impacted by lower sales of Increlex® further to the management of the anticipated shortage period. Sales in North America represented 5.6% of total consolidated Group sales, a stable ratio year-on-year.

In the first quarter 2013, sales generated in the **Rest of the World** reached €80.1 million, up 27.6% year-on-year excluding foreign exchange impacts[1]. This performance was mainly driven by strong volume growth in China (notably Decapeptyl®), in Australia (where the Group signed an agreement in April 2012 with Galderma for the distribution of Dysport® in aesthetic use), in Algeria and in Vietnam. Sales in the Rest of the World reached 26.1% of total consolidated Group sales in the quarter compared to 21.8% the previous year.

[1] Variations excluding foreign exchange impacts are computed by restating the first three months of 2012 with the first three months of 2013 average exchange rates

***Sales by therapeutic area and by product***

The following table shows sales by therapeutic area and by product for the first quarter 2013 and 2012:

| | First Quarter | | | |
|---|---|---|---|---|
| (in million euros) | 2013 | 2012 | % Variation | % Variation at constant currency |
| Uro-oncology | **74.3** | **71.0** | **4.6%** | **4.7%** |
| of which Hexvix® | 4.0 | 3.0 | 33.7 | 33.7% |
| of which Decapeptyl® | 70.2 | 68.0 | 3.3% | 3.4% |
| Endocrinology | **81.9** | **74.0** | **10.6%** | **10.8%** |
| of which Somatuline® | 61.5 | 54.7 | 12.4% | 12.6% |
| of which NutropinAq® | 14.1 | 13.1 | 7.5% | 7.6% |
| of which Increlex® | 6.3 | 6.2 | 1.2% | 2.1% |
| Neurology | **60.8** | **57.4** | **5.9%** | **8.4%** |
| of which Dysport® | 60.8 | 57.4 | 5.9% | 8.4% |
| **Specialty Care** | **217.0** | **202.4** | **7.2%** | **8.0%** |
| Gastroenterology | **53.7** | **44.6** | **20.4%** | **20.3%** |
| of which Smecta® | 29.7 | 26.6 | 11.4% | 11.2% |
| of which Forlax® | 8.9 | 9.9 | (10.6%) | (10.6%) |
| Cognitive Disorders | **17.4** | **23.0** | **(24.2%)** | **(24.0%)** |
| of which Tanakan® | 17.4 | 23.0 | (24.2%) | (24.0%) |
| Cardiovascular | **6.2** | **11.0** | **(43.9%)** | **(43.9%)** |
| of which Nisis & Nisisco® | 2.0 | 6.9 | (71.5%) | (71.5%) |
| of which Ginkor® | 4.2 | 3.2 | 32.0% | 32.0% |
| Other Primary Care | **3.1** | **3.3** | **(6.9%)** | **(6.9%)** |
| of which Adrovance® | 2.6 | 3.0 | (14.5%) | (14.5%) |
| **Primary Care** | **80.4** | **81.9** | **(1.9%)** | **(1.9%)** |
| **Total Drug Sales** | **297.3** | **284.4** | **4.6%** | **5.1%** |
| **Drug-related Sales**[1] | **9.3** | **8.4** | **10.7%** | **11.5%** |
| **Group Sales** | **306.6** | **292.8** | **4.7%** | **5.3%** |

In the first quarter 2013, sales of **Specialty Care products** reached €217.0 million, up 8.0% year-on-year excluding foreign exchange impacts[2]. Sales in endocrinology, neurology and uro-oncology grew year-on-year by 10.8%, 8.4% and 4.7%, respectively, excluding foreign exchange impacts[2]. The relative weight of Specialty Care products continued to increase in the quarter to reach 70.8% of total Group sales, compared to 69.1% the previous year.

**In uro-oncology,** sales of **Decapeptyl®** reached €70.2 million in the first quarter 2013, up 3.4% year-on-year excluding foreign exchange impacts[2]. Strong volume growth in China and solid sales growth in Italy, Russia and the United Kingdom, were partly offset by lower sales in France where market is under pressure, and price pressure in Poland. In the first quarter 2013, sales of **Hexvix®** amounted to €4.0 million, mostly generated in Germany. Sales in uro-oncology represented 24.2% of total Group sales, a stable ratio year-on-year.

[1] Active ingredients and raw materials
[2] Variations excluding foreign exchange impacts are computed by restating the first three months of 2012 with the first three months of 2013 average exchange rates

**In endocrinology,** sales continued to grow, reaching €81.9 million in the first quarter 2013, up 10.8% year-on-year excluding foreign exchange impacts[2], representing 26.7% of total Group sales, compared to 25.3% in the previous year.

**Somatuline®** – In the first quarter 2013, sales reached €61.5 million, up 12.6% excluding foreign exchange impacts[1], fuelled by strong growth in the United States, Mexico, Germany and France, where we noticed a dynamic trend.

**NutropinAq®** – In the first quarter 2013, sales totalled €14.1 million, up 7.6% excluding foreign exchange impacts[1], driven by strong performance in Germany, France and the Netherlands.

**Increlex®** – In the first quarter 2013, sales amounted to €6.3 million, up 2.1% excluding foreign exchange impacts[1]. In North America, sales of Increlex® were negatively affected by the management of the anticipated shortage period, partly offset by the positive impact of the recognition of the paediatric use of Increlex® by the Centre for Medicare and Medicaid Services (CMS) in the US, allowing for a reduced compulsory rebate (17% rebate instead of 23%).

**In neurology, Dysport®** sales reached €60.8 million in the first quarter 2013, up 8.4% year-on-year excluding foreign exchange impacts[1], representing 19.8% of total Group sales, compared to 19.6% the previous year. The growth was mainly driven by a strong sales growth in Russia and Australia.

In the first quarter 2013, sales of **Primary Care products** amounted to €80.4 million, down 1.9% year-on-year excluding foreign exchange impacts[1], negatively impacted by the consequences of a tougher competitive environment in France and by the step-up during the summer 2012 of the regulation known as "Tiers-Payant[2]", partly offset by strong international sales growth. In the first quarter 2013, primary care sales represented 26.2% of the Group's consolidated sales compared to 28.0% the previous year. Primary Care sales in France represented 35.0% of total Group Primary Care sales, compared to 46.3% the previous year.

**In gastroenterology,** sales reached €53.7 million, up 20.3% year-on-year excluding foreign exchange impacts[1], driven notably by anticipated orders in Vietnam ahead of import license renewal and by a favourable comparison basis related to Etiasa® in China in the first quarter 2012.

**Smecta®** – In the first quarter 2013, sales reached €29.7 million, up 11.2% year-on-year excluding foreign exchange impacts[1], resulting from a gastroenteritis epidemy larger than the previous year in Europe and from a solid growth in China. Smecta® sales represented 9.7% of total Group sales over the period compared to 9.1% the previous year.

**Forlax®** – In the first quarter 2013, sales amounted to €8.9 million, down 10.6% year-on-year excluding foreign exchange impacts[1], mainly penalized by the step-up of the regulation known as "Tiers-Payant[2]" and the change of distribution model in Italy (mentioned above). France represented 60.8% of total product sales in the quarter, compared to 61.2% the previous year.

**In the cognitive disorders area,** sales of **Tanakan®** in the first quarter 2013 reached €17.4 million, down 24.0% year-on-year excluding foreign exchange impacts[1], penalized by the delisting of the product in France as of 1st March 2012 and in Romania in May 2012, partly offset by solid sales growth in Russia. In the first quarter 2013, 25.9% of Tanakan® sales were made in France compared with 40.3% the previous year.

**In the cardiovascular area,** sales in the first quarter 2013 amounted to €6.2 million, down 43.9% year-on-year, mainly impacted by the 71.5% decline in Nisis®/Nisisco® sales following the arrival of several generics and a 15% price cut in November 2011, and by the step-up of the regulation known as "Tiers-Payant[2]" in July 2012.

[1] Variations excluding foreign exchange impacts are computed by restating the first three months of 2012 with the first three months of 2013 average exchange rates

[2] « Tiers-Payant » regulation: the patient now pays upfront for a branded drug and is later reimbursed

Sales of **Other primary care products** reached €3.1 million in the first quarter 2013, down 6.9% year-on-year excluding foreign exchange impacts[1], mainly impacted by the decline in **Adrovance®** sales of 14.5% excluding foreign exchange impacts[1].

In the first quarter 2013, **drug-related sales (active ingredients and raw materials)** reached €9.3 million, up 11.5% year-on-year excluding foreign exchange impacts[1].

[1] Variations excluding foreign exchange impacts are computed by restating the first three months of 2012 with the first three months of 2013 average exchange rates