

## Ipsen announces new data to be presented at ASCO in line with its continued commitment to Oncology research

Paris (France), 1<sup>st</sup> June 2017 – Ipsen (Euronext: IPN; ADR: IPSEY) today announced that lanreotide (Somatuline<sup>®</sup> Autogel<sup>®</sup> Depot), cabozantinib (Cabometyx<sup>®</sup>), irinotecan liposome injection (Onivyde<sup>®</sup>) and the investigational compounds <sup>177</sup>Lu-OPS201 and <sup>68</sup>Ga-OPS201 are the subject of presentations at the American Society of Clinical Oncology (ASCO) 2017 conference. The meeting takes place in Chicago, Illinois, June 2-6, 2017.

*“Ipsen continues to build on the strength of its Oncology portfolio at ASCO this year with new data being presented to support our key products as well as our early-stage radiopharmaceutical compounds”* said **David Meek, Chief Executive Officer, Ipsen**. *“We are establishing a leadership position in several specialty Oncology markets and will continue to collaborate with the research community to accelerate the discovery and development of therapeutic options with the goal of improving the lives of people living with cancer.”*

*“These studies demonstrate Ipsen’s steadfast commitment to cancer patients for whom innovative options are urgently needed”* said **Alexandre Lebeaut, MD, Executive Vice-President, R&D, Chief Scientific Officer, Ipsen**. *“Researchers are sharing deeper insights from Ipsen’s oncology’s portfolio to continue to improve treatment of gastroenteropancreatic neuroendocrine tumors, advanced pancreatic cancer and advanced renal cell carcinoma.”*

Abstracts on the following topics will be presented beginning Saturday, June 3, 2017 in McCormick Place, Hall A (unless otherwise specified):

### **Lanreotide (Somatuline<sup>®</sup> Autogel<sup>®</sup>) is featured in 3 abstracts:**

**Saturday, June 3 - 8:00 AM - 11:30 AM**

Poster Session - Track: Gastrointestinal (Noncolorectal) Cancer

- Presenter: George A. Fisher, Stanford University  
Lanreotide depot (LAN) for symptomatic control of carcinoid syndrome (CS) in neuroendocrine tumor (NET) patients previously responsive to octreotide (OCT): Subanalysis of patient-reported symptoms from the phase III ELECT study.  
Abstract #4088 - Poster Board #80
- Presenter: Edward M. Wolin, Montefiore Einstein Cancer Center  
Final progression-free survival (PFS) analyses for lanreotide autogel/depot 120 mg in metastatic enteropancreatic neuroendocrine tumors (NETs): The CLARINET extension study.  
Abstract #4089 - Poster Board #81
- Presenter: Alexandria T. Phan, University of New Mexico Comprehensive Cancer Center  
Effect of lanreotide depot (LAN) on 5-hydroxyindoleacetic acid (5HIAA) and chromogranin A (CgA) in gastroenteropancreatic neuroendocrine (GEP NET) tumors: Correlation with tumor response and progression-free survival (PFS) from the phase III CLARINET study.  
Abstract #4095 - Poster Board #87

**Cabozantinib (Cabometyx®) is featured in 12 abstracts selected for e-publication, poster sessions or oral poster presentations:**

**Saturday, June 3 - 8:00-11:30 AM**

Poster Session - Lung Cancer—Non-Small Cell Metastatic

- Presenter: Drilon, Memorial Sloan-Kettering Cancer Center  
Baseline frequency of brain metastases and outcomes with multikinase inhibitor therapy in patients with RET-rearranged lung cancers.  
Abstract 9069 – Poster board #395  
Note: *This is an investigator-sponsored trial*

**Saturday, June 3 1:15-4:45 PM**

Poster Session - Tumor Biology

- Presenter: Smith, Northwestern University Feinberg School of Medicine  
Role of ERBB signaling in RET-rearranged lung cancer and contribution of EGFR amplification to cabozantinib resistance.  
Abstract 11583 – Poster board #283  
Note: *This is an investigator-sponsored trial*

Poster Session - Gynecologic Cancer

- Presenter: Dhani, Princess Margaret Cancer Centre, University Health Network  
Phase II study of cabozantinib (cabo) in patients (pts) with recurrent/metastatic endometrial cancer (EC): A study of the Princess Margaret, Chicago, and California phase II consortia.  
Abstract 5524 – Poster #346  
*Discussed at the Poster Discussion Session on Saturday, June 3, 2017, 4:45 PM - 6:00 PM, at Arie Crown Theater*  
Note: *This is an investigator-sponsored trial*
- Presenter: Mandilaras, McGill University Health Centre  
Exploratory phase II evaluation of cabozantinib in recurrent/metastatic uterine carcinosarcoma (CS): A study of the Princess Margaret, Chicago, and California phase II consortia  
Abstract: 5587 – Poster board #409  
Note: *This is an investigator-sponsored trial*

**Saturday, June 3 1:15-4:15 PM**

Oral Abstract Session - Genitourinary (Prostate) Cancer

- Presenter: Heller, Memorial Sloan-Kettering Cancer Center  
Circulating tumor cell (CTC) number as a response endpoint in metastatic castration resistant (mCRPC) compared with PSA across five randomized phase 3 trials.  
Abstract 5007 [3.27-3.39 PM], Hall B1

**Sunday, June 4 8:00-11:30 AM**

Poster Session - Track: Genitourinary (Non-Prostate) Cancer

- Presenter: Apolo, National Cancer Institute, National Institutes of Health  
A phase I study of cabozantinib plus nivolumab (CaboNivo) and cabonivo plus ipilimumab (CaboNivolpi) in patients (pts) with refractory metastatic (m) urothelial carcinoma (UC) and other genitourinary (GU) tumors.  
Abstract: 4562 – Poster Board #240  
Note: *This is an investigator-sponsored trial*

- Presenter: Tannir, The University of Texas MD Anderson Cancer Center  
Clinical outcomes by nephrectomy status in METEOR, a randomized phase 3 trial of cabozantinib (cabo) vs everolimus (eve) in patients (pts) with advanced renal cell carcinoma (RCC).  
Abstract 4570 – Poster Board #248
- Presenter: Donskov, Aarhus University Hospital  
Outcomes based on age in the phase 3 METEOR trial of cabozantinib (cabo) vs everolimus (eve) in patients with advanced renal cell carcinoma (RCC).  
Abstract 4578 – Poster Board #256
- Presenter: Pal, City of Hope Comprehensive Cancer Center  
A randomized, phase II efficacy assessment of multiple MET kinase inhibitors in metastatic papillary renal carcinoma (PRCC): SWOG S1500.  
Abstract TPS4599 – Poster Board #272b  
Note: *This is an investigator-sponsored trial*

Monday, June 5 1:15-4:45 PM

Poster Session - Genitourinary (Prostate) Cancer

- Presenter: Posadas, Samuel Oschin Comprehensive Cancer Institute, Cedars-Sinai Medical Center  
Circulating tumor cell subsets and macrophage polarization to predict efficacy of cabozantinib in advanced prostate cancer with visceral metastases.  
Abstract 5031 – Poster Board #105  
Note: *This is an investigator-sponsored trial*

E-publication of the following abstracts

- Jeffrey Lin, Amir Mortazavi, Mark N. Stein et al.  
Combined FDG and NaF PET/CT study in patients (pts) with metastatic genitourinary tumors (mGU) treated with cabozantinib + nivolumab +/- ipilimumab (CaboNivo+/-Ipi).  
epublication of the abstract [e16017]
- Bhavana Konda, Michael V. Knopp, Peter R. Martin et al.  
Effect of cabozantinib on bone turnover markers (BTM) and bone metastases (BM) in radioiodine refractory (RAIR)-differentiated thyroid cancer (DTC).  
epublication of the abstract [e17580]

**Irinotecan liposome injection (Onivyde®) is featured in 2 abstracts, one of which is selected for poster presentation:**

Saturday, June 3 8:00 AM - 11:30 AM

Poster Session - Gastrointestinal (Non-Colorectal) Cancer

- Presenter: Teresa Mercade Macarulla, Vall d'Hebron University Hospital Institute of Oncology (VHIO)  
Subgroup analysis by prior lines of metastatic therapy (mtx) in NAPOLI- 1: A global, randomized phase 3 study of liposomal irinotecan (nal- IRI) ± 5- fluorouracil and leucovorin (5- FU/LV), vs. 5- FU/LV in patients (pts) with metastatic pancreatic ductal adenocarcinoma (mPDAC) who have progressed following gemcitabine-based therapy.  
Abstract 4127 - Poster Board: #119

E-publication of the following abstract

- Andrea Wang-Gillam, Li-Tzong Chen, Chung-Pin Li, et al.  
The prognostic value of baseline neutrophil-to-lymphocyte ratio (NLR) and platelet-to-lymphocyte ratio (PLR) for predicting clinical outcome in patients with metastatic pancreatic ductal adenocarcinoma (mPDAC) treated with liposomal irinotecan (nal-IRI; MM-398) + 5-fluorouracil and leucovorin (5-FU/LV) vs 5-FU/LV.  
epublication of the abstract [e17595]

### **Satoreotide**

Saturday, June 3 - 8:00 AM - 11:30 AM

Poster Session - Track: Gastrointestinal (Noncolorectal) Cancer

- Presenter: Diane Lauren Reidy, Weill Cornell Medical College  
Theranostic trial of well differentiated neuroendocrine tumors (NETs) with somatostatin antagonists <sup>68</sup>Ga-OPS201 and <sup>177</sup>Lu-OPS201.  
Abstract #4094 - Poster Board #86  
Note: *This is an investigator-sponsored trial (MSKCC)*

Nota bene: Approved indications for products vary by country and not all indications are available in every country. The product safety and efficacy profiles have not yet been established outside the approved indications.

The investigational compounds Lu-OPS201 and Ga-OPS201 are not approved in the U.S. Ipsen has exclusive commercialization rights for current and potential future cabozantinib indications outside of the United States and Japan.

### **INDICATION**

Somatuline® Depot (lanreotide) Injection 120 mg is indicated for the treatment of adult patients with unresectable, well- or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival.

### **IMPORTANT SAFETY INFORMATION**

#### **Contraindications:**

Somatuline is contraindicated in patients with hypersensitivity to lanreotide. Allergic reactions (including angioedema and anaphylaxis) have been reported following administration of lanreotide.

#### **Warnings and Precautions:**

- Cholelithiasis and Gallbladder Sludge: Somatuline may reduce gallbladder motility and lead to gallstone formation. Periodic monitoring may be needed.
- Hypoglycemia or Hyperglycemia: Pharmacological studies show that Somatuline, like somatostatin and other somatostatin analogs, inhibits the secretion of insulin and glucagon. Blood glucose levels should be monitored when Somatuline treatment is initiated, or when the dose is altered, and antidiabetic treatment should be adjusted accordingly.
- Cardiac Abnormalities: Somatuline may decrease heart rate. In 81 patients with baseline heart rates of  $\geq 60$  beats per minute (bpm) treated with Somatuline DEPOT in the GEPNETs clinical trial, the incidence of heart rate  $< 60$  bpm was 23% (19/81) with Somatuline vs 16% (15/94) with placebo; 10 patients (12%) had documented heart rates  $< 60$  bpm on more than



one visit. The incidence of documented episodes of heart rate < 50 bpm or bradycardia reported as an adverse event was 1% in each treatment group. Initiate appropriate medical management in patients who develop symptomatic bradycardia.

In patients without underlying cardiac disease, Somatuline may lead to a decrease in heart rate without necessarily reaching the threshold of bradycardia. In patients suffering from cardiac disorders prior to treatment, sinus bradycardia may occur. Care should be taken when initiating treatment in patients with bradycardia.

- **Drug Interactions:** The pharmacological gastrointestinal effects of Somatuline may reduce the intestinal absorption of concomitant drugs. Concomitant administration of Somatuline Depot may decrease the relative bioavailability of cyclosporine and may necessitate the adjustment of cyclosporine dose to maintain therapeutic levels.

#### **Adverse Reactions:**

In the GEP-NET pivotal trial, the most common adverse reactions (incidence >10% and more common than placebo) in patients treated with Somatuline DEPOT vs placebo were abdominal pain (34% vs 24%), musculoskeletal pain (19% vs 13%), vomiting (19% vs 9%), headache (16% vs 11%), injection site reaction (15% vs 7%), hyperglycemia (14% vs 5%), hypertension (14% vs 5%), and cholelithiasis (14% vs 7%).

You may report suspected adverse reactions to FDA at 1-800-FDA-1088 or to Ipsen Biopharmaceuticals, Inc. at 1-888-980-2889.

Please see the full Prescribing Information for Somatuline® Depot by accessing the following [link](#).

#### **About ONIVYDE®**

ONIVYDE® is an encapsulated formulation of irinotecan. This long-circulating liposomal form is designed to increase length of tumor exposure to both irinotecan and its active metabolite, SN- 38. ONIVYDE® was approved by the U.S. FDA in combination with fluorouracil and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy. For full prescribing information, including Boxed WARNING, please visit [www.ONIVYDE.com](http://www.ONIVYDE.com).

#### **INDICATION**

ONIVYDE® (irinotecan liposome injection) is indicated, in combination with fluorouracil (5-FU) and leucovorin (LV), for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy. Limitation of Use: ONIVYDE® is not indicated as a single agent for the treatment of patients with metastatic adenocarcinoma of the pancreas.

#### **IMPORTANT SAFETY INFORMATION - UNITED STATES**

##### **WARNING: SEVERE NEUTROPENIA and SEVERE DIARRHEA**

Fatal neutropenic sepsis occurred in 0.8% of patients receiving ONIVYDE®. Severe or life threatening neutropenic fever or sepsis occurred in 3% and severe or life-threatening neutropenia occurred in 20% of patients receiving ONIVYDE® in combination with fluorouracil (5-FU) and



leucovorin (LV). Withhold ONIVYDE® for absolute neutrophil count below 1500/mm<sup>3</sup> or neutropenic fever. Monitor blood cell counts periodically during treatment.

Severe diarrhea occurred in 13% of patients receiving ONIVYDE® in combination with 5-FU/LV. Do not administer ONIVYDE® to patients with bowel obstruction. Withhold ONIVYDE® for diarrhea of Grade 2-4 severity.

### **CONTRAINDICATION**

ONIVYDE® is contraindicated in patients who have experienced a severe hypersensitivity reaction to ONIVYDE® or irinotecan HCl.

### **WARNINGS AND PRECAUTIONS**

#### **Severe Neutropenia**

ONIVYDE® can cause severe or life-threatening neutropenia and fatal neutropenic sepsis. In a clinical study, the incidence of fatal neutropenic sepsis was 0.8% among patients receiving ONIVYDE®, occurring in 1/117 patients in the ONIVYDE®/5-FU/LV arm and 1/147 patients receiving ONIVYDE® as a single agent. Severe or life-threatening neutropenia occurred in 20% of patients receiving ONIVYDE®/5-FU/LV vs 2% of patients receiving 5-FU/LV. Grade 3/4 neutropenic fever/neutropenic sepsis occurred in 3% of patients receiving ONIVYDE®/5-FU/LV, and did not occur in patients receiving 5-FU/LV.

In patients receiving ONIVYDE®/5-FU/LV, the incidence of Grade 3/4 neutropenia was higher among Asian (18/33 [55%]) vs White patients (13/73 [18%]). Neutropenic fever/neutropenic sepsis was reported in 6% of Asian vs 1% of White patients.

#### **Severe Diarrhea**

ONIVYDE® can cause severe and life-threatening diarrhea. Do not administer ONIVYDE® to patients with bowel obstruction. Severe and life-threatening late-onset (onset > 24 hours after chemotherapy) and early-onset diarrhea (onset ≤24 hours after chemotherapy, sometimes with other symptoms of cholinergic reaction) were observed. An individual patient may experience both early- and late-onset diarrhea.

In a clinical study, Grade 3/4 diarrhea occurred in 13% of patients receiving ONIVYDE®/5-FU/LV vs 4% receiving 5-FU/LV. Grade 3/4 late-onset diarrhea occurred in 9% of patients receiving ONIVYDE®/5-FU/LV vs 4% in patients receiving 5-FU/LV; the incidences of early-onset diarrhea were 3% and no Grade 3/4 incidences, respectively. Of patients receiving ONIVYDE®/5-FU/LV, 34% received loperamide for late-onset diarrhea and 26% received atropine for early-onset diarrhea.

#### **Interstitial Lung Disease (ILD)**

Irinotecan HCl can cause severe and fatal ILD. Withhold ONIVYDE® in patients with new or progressive dyspnea, cough, and fever, pending diagnostic evaluation. Discontinue ONIVYDE® in patients with a confirmed diagnosis of ILD.

#### **Severe Hypersensitivity Reactions**

Irinotecan HCl can cause severe hypersensitivity reactions, including anaphylactic reactions. Permanently discontinue ONIVYDE® in patients who experience a severe hypersensitivity reaction.

#### **Embryo-Fetal Toxicity**



Based on animal data with irinotecan HCl and the mechanism of action of ONIVYDE®, ONIVYDE® can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during and for 1 month after ONIVYDE® treatment.

## **ADVERSE REACTIONS**

- The most common ( $\geq 20\%$ ) adverse reactions in which patients receiving ONIVYDE®/5-FU/LV experienced a  $\geq 5\%$  higher incidence of any Grade vs the 5-FU/LV arm, were diarrhea (any 59%, 26%; severe 13%, 4%) (early diarrhea [any 30%, 15%; severe 3%, 0%], late diarrhea [any 43%, 17%; severe 9%, 4%]), fatigue/asthenia (any 56%, 43%; severe 21%, 10%), vomiting (any 52%, 26%; severe 11%, 3%), nausea (any 51%, 34%; severe 8%, 4%), decreased appetite (any 44%, 32%; severe 4%, 2%), stomatitis (any 32%, 12%; severe 4%, 1%), pyrexia (any 23%, 11%; severe 2%, 1%).
- Of less common ( $< 20\%$ ) adverse reactions, patients receiving ONIVYDE®/5-FU/LV who experienced Grade 3/4 adverse reactions at a  $\geq 2\%$  higher incidence of Grade 3/4 toxicity vs the 5-FU/LV arm, respectively, were sepsis (3%, 1%), neutropenic fever/neutropenic sepsis (3%, 0%), gastroenteritis (3%, 0%), intravenous catheter-related infection (3%, 0%), weight loss (2%, 0%), and dehydration (4%, 2%).
- The laboratory abnormalities in which patients receiving ONIVYDE®/5-FU/LV experienced a  $\geq 5\%$  higher incidence vs the 5-FU/LV arm, were anemia (any 97%, 86%; severe 6%, 5%), lymphopenia (any 81%, 75%; severe 27%, 17%), neutropenia (any 52%, 6%; severe 20%, 2%), thrombocytopenia (any 41%, 33%; severe 2%, 0%), increased alanine aminotransferase (any 51%, 37%; severe 6%, 1%), hypoalbuminemia (any 43%, 30%; severe 2%, 0%), hypomagnesemia (any 35%, 21%; severe 0%, 0%), hypokalemia (any 32%, 19%; severe 2%, 2%), hypocalcemia (any 32%, 20%; severe 1%, 0%), hypophosphatemia (any 29%, 18%; severe 4%, 1%), hyponatremia (any 27%, 12%; severe 5%, 3%), increased creatinine (any 18%, 13%; severe 0%, 0%).
- ONIVYDE® can cause cholinergic reactions manifesting as rhinitis, increased salivation, flushing, bradycardia, miosis, lacrimation, diaphoresis, and intestinal hyperperistalsis with abdominal cramping and early-onset diarrhea. Grade 1/2 cholinergic symptoms other than early diarrhea occurred in 12 (4.5%) ONIVYDE®-treated patients.
- Infusion reactions, consisting of rash, urticaria, periorbital edema, or pruritus, occurring on the day of ONIVYDE® administration were reported in 3% of patients receiving ONIVYDE® or ONIVYDE®/5-FU/LV.
- The most common serious adverse reactions ( $\geq 2\%$ ) of ONIVYDE® were diarrhea, vomiting, neutropenic fever or neutropenic sepsis, nausea, pyrexia, sepsis, dehydration, septic shock, pneumonia, acute renal failure, and thrombocytopenia.

## **DRUG INTERACTIONS**

Avoid the use of strong CYP3A4 inducers, if possible, and substitute non-enzyme-inducing therapies  $\geq 2$  weeks prior to initiation of ONIVYDE®. Avoid the use of strong CYP3A4 or UGT1A1 inhibitors, if possible, and discontinue strong CYP3A4 inhibitors  $\geq 1$  week prior to starting therapy.



## USE IN SPECIFIC POPULATIONS

### **Pregnancy and Reproductive Potential**

Advise pregnant women of the potential risk to a fetus. Advise males with female partners of reproductive potential to use effective contraception during and for 4 months after ONIVYDE® treatment.

### **Lactation**

Advise nursing women not to breastfeed during and for 1 month after ONIVYDE® treatment.

### **Pediatric**

Safety and effectiveness of ONIVYDE® have not been established in pediatric patients.

## DOSAGE AND ADMINISTRATION

The recommended dose of ONIVYDE® is 70 mg/m<sup>2</sup> intravenous (IV) infusion over 90 minutes every 2 weeks, administered prior to LV and 5-FU. The recommended starting dose of ONIVYDE® in patients known to be homozygous for the UGT1A1\*28 allele is 50 mg/m<sup>2</sup> administered by IV infusion over 90 minutes. There is no recommended dose of ONIVYDE® for patients with serum bilirubin above the upper limit of normal. Premedicate with a corticosteroid and an anti-emetic 30 minutes prior to ONIVYDE®. Withhold ONIVYDE® for Grade 3/4 adverse reactions. Resume ONIVYDE® with reduced dose once adverse reaction recovered to ≤Grade 1. Discontinue ONIVYDE® in patients who experience a severe hypersensitivity reaction and in patients with a confirmed diagnosis of ILD.

Do not substitute ONIVYDE® for other drugs containing irinotecan HCl.

Please see full U.S. [Prescribing Information](#) for ONIVYDE®.

## About Ipsen

Ipsen is a global specialty-driven pharmaceutical group with total sales close to €1.6 billion in 2016. Ipsen sells more than 20 drugs in more than 115 countries, with a direct commercial presence in more than 30 countries. Ipsen's ambition is to become a leader in specialty healthcare solutions for targeted debilitating diseases. Its fields of expertise cover oncology, neurosciences and endocrinology (adult & pediatric). Ipsen's commitment to oncology is exemplified through its growing portfolio of key therapies improving the care of patients suffering from prostate cancer, neuro-endocrine tumors, renal cell carcinoma and pancreatic cancer. Ipsen also has a significant presence in primary care. Moreover, the Group has an active policy of partnerships. Ipsen's R&D is focused on its innovative and differentiated technological platforms, peptides and toxins, located in the heart of the leading biotechnological and life sciences hubs (Les Ulis/Paris-Saclay, France; Slough/Oxford, UK; Cambridge, US). In 2016, R&D expenditures exceeded €200 million. The Group has more than 4,900 employees worldwide. Ipsen's shares are traded on segment A of Euronext Paris (stock code: IPN, ISIN code: FR0010259150) and are eligible to the "Service de Règlement Différé" ("SRD"). The Group is part of the SBF 120 index. Ipsen has implemented a Sponsored Level I American Depositary Receipt (ADR) program, which trades on the over-the-counter market in the United States under the symbol IPSEY. For more information on Ipsen, visit [www.ipсен.com](http://www.ipсен.com).



### **Ipsen Forward Looking Statement**

The forward-looking statements, objectives and targets contained herein are based on the Group's management strategy, current views and assumptions. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated herein. All of the above risks could affect the Group's future ability to achieve its financial targets, which were set assuming reasonable macroeconomic conditions based on the information available today. Use of the words "believes," "anticipates" and "expects" and similar expressions are intended to identify forward-looking statements, including the Group's expectations regarding future events, including regulatory filings and determinations. Moreover, the targets described in this document were prepared without taking into account external growth assumptions and potential future acquisitions, which may alter these parameters. These objectives are based on data and assumptions regarded as reasonable by the Group. These targets depend on conditions or facts likely to happen in the future, and not exclusively on historical data. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties, notably the fact that a promising product in early development phase or clinical trial may end up never being launched on the market or reaching its commercial targets, notably for regulatory or competition reasons. The Group must face or might face competition from generic products that might translate into a loss of market share. Furthermore, the Research and Development process involves several stages each of which involves the substantial risk that the Group may fail to achieve its objectives and be forced to abandon its efforts with regards to a product in which it has invested significant sums. Therefore, the Group cannot be certain that favourable results obtained during pre-clinical trials will be confirmed subsequently during clinical trials, or that the results of clinical trials will be sufficient to demonstrate the safe and effective nature of the product concerned. There can be no guarantees a product will receive the necessary regulatory approvals or that the product will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Other risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the Group's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the Group's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions. The Group also depends on third parties to develop and market some of its products which could potentially generate substantial royalties; these partners could behave in such ways which could cause damage to the Group's activities and financial results. The Group cannot be certain that its partners will fulfil their obligations. It might be unable to obtain any benefit from those agreements. A default by any of the Group's partners could generate lower revenues than expected. Such situations could have a negative impact on the Group's business, financial position or performance. The Group expressly disclaims any obligation or undertaking to update or revise any forward looking statements, targets or estimates contained in this press release to reflect any change in events, conditions, assumptions or circumstances on which any such statements are based, unless so required by applicable law. The Group's business is subject to the risk factors outlined in its registration documents filed with the French Autorité des Marchés Financiers.



The risks and uncertainties set out are not exhaustive and the reader is advised to refer to the Group's 2016 Registration Document available on its website ([www.ipsen.com](http://www.ipsen.com)).

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