

## **New investigational clinical data for Ipsen’s oncology products in 11 solid tumor types to be presented at 2019 ASCO Annual Meeting**

**Paris (France), 24 May 2019** – Ipsen (Euronext: IPN; ADR: IPSEY) today announced that new data from clinical studies on investigational uses of cancer medicines cabozantinib (Cabometyx®), liposomal irinotecan (Onivyde®), and lanreotide autogel (Somatuline®, marketed as Somatuline Depot® in the United States) will be presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting. The meeting takes place in Chicago, Illinois, U.S., 31 May–4 June 2019; data featuring Ipsen medicines includes:

- **New data from the Phase 3 CELESTIAL** trial on the association of adverse events with efficacy outcomes for cabozantinib in patients with advanced hepatocellular carcinoma
- **Overview of the Phase 3 COSMIC-312** trial of cabozantinib in combination with atezolizumab vs sorafenib in patients with advanced hepatocellular carcinoma who have not received previous systemic anticancer therapy
- **First Phase 2 data** from the CaboGIST study (trial 1317) from the European Organization for Research and Treatment of Cancer on the activity and safety of cabozantinib in patients with metastatic gastrointestinal stromal tumor after failure of imatinib and sunitinib
- **Preliminary results** from the RESILIENT study of liposomal irinotecan injection in patients with small cell lung cancer
- **Results from a Phase 2 multicenter study** of lanreotide autogel in the treatment of clinical symptoms associated with inoperable malignant intestinal obstruction

“At Ipsen, patients inspire and drive us to tackle some of the most difficult-to-treat cancers, particularly where few effective options exist. ASCO gives us the opportunity to share the progress we have made in our mission of developing and delivering therapeutic solutions that meet the real needs of patients and may help improve their lives,” said Dr. Alexandre Lebeaut, Ipsen’s Executive Vice President, R&D, and Chief Scientific Officer. “With our continued clinical programs and collaborations, we are making strides in renal, liver and small cell lung cancers and other cancers with high unmet need, and we look forward to continuing to advance these programs.”

Follow Ipsen on Twitter via @IpsenGroup and @IpsenUS and keep up to date with ASCO 2019 congress news and updates by using the hashtag #ASCO19.

**Overview of key Ipsen presentations at ASCO 2019:**

Medicine	Abstract title	Abstract number/timing (CDT)
Cabometyx® (cabozantinib)	Phase 3 (COSMIC-311) randomized, double-blind, placebo-controlled study of cabozantinib in patients with radioiodine (RAI)-refractory differentiated thyroid cancer (DTC) who have progressed after prior VEGFR-targeted therapy	Abstract TPS6097 Poster 82a – Category: Head and Neck Cancer; Saturday, 1 June, 1:15 PM - 4:15 PM; Hall A TIP
	Association of adverse events (AEs) with efficacy outcomes for cabozantinib (C) in patients (pts) with advanced hepatocellular carcinoma (aHCC) in the Phase 3 CELESTIAL trial	Abstract 4088 Poster 193 – Category: Gastrointestinal (Noncolorectal) Cancer; Monday, 3 June, 8:00 AM - 11:00 AM; Hall A
	Phase 3 (COSMIC-312) study of cabozantinib (C) in combination with atezolizumab (A) vs sorafenib (S) in patients (pts) with advanced hepatocellular carcinoma (aHCC) who have not received previous systemic anticancer therapy	Abstract TPS4157 Poster 254a – Category: Gastrointestinal (Noncolorectal) Cancer; Monday, 3 June, 8:00 AM - 11:00 AM; Hall A TIP
Onivyde® (nal-IRI/liposomal irinotecan)	RESILIENT: Study of Irinotecan Liposome Injection (nal-IRI) in Patients with Small Cell Lung Cancer: Preliminary Findings from Part 1 Dose-defining Phase	Abstract 8562 Poster 318 – Category: Lung Cancer—Non-Small Cell Local-Regional/Small Cell/Other Thoracic Cancers; Poster - Sunday, 2 June, 8:00 AM - 11:00 AM; Hall A
Somatuline® Autogel® (lanreotide autogel/depot)	Efficacy and Safety of Lanreotide Autogel (LAN) 120 mg in the Treatment of Clinical Symptoms Associated With Inoperable Malignant Intestinal Obstruction	Abstract 4118 Poster 223 – Category: Gastrointestinal (Noncolorectal) Cancer; Poster - Monday, 3 June,

	(IMIO): Results From A Phase II Multicenter Study	8:00 AM - 11:00 AM; Hall A
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**Overview of key investigator sponsored study presentations featuring Ipsen medicines at ASCO 2019:**

Medicine	Abstract title	Abstract number/timing (CDT)
Cabometyx® (cabozantinib)	Activity and safety of cabozantinib in patients with metastatic gastrointestinal stromal tumor after failure of imatinib and sunitinib. European Organization for Research and Treatment of Cancer (EORTC) Phase 2 trial 1317 “CaboGIST” <i>EORTC Sponsored Study</i>	Abstract 11006 Oral: Category: Sarcoma; Monday, 3 June, 10:00 AM - 10:12 AM; E450
	PDIGREE: An adaptive Phase 3 trial of PD-inhibitor nivolumab and Ipilimumab (IPI-NIVO) with VEGF TKI cabozantinib (CABO) in metastatic untreated Renal Cell Cancer (Alliance A031704) <i>NCI Sponsored Study</i>	Abstract TPS4596 Poster 417a – Category: Genitourinary (Nonprostate) Cancer; Poster - Monday, 3 June, 1:15 PM - 4:15 PM; Hall A
	Prognostic value of sequential 18F-FDG + Na18F PET/CT (NaF+FDG PET) in metastatic genitourinary (GU) cancer patients (pts) treated with Cabozantinib/ Nivolumab +/- Ipilimumab (CaboNivolpi) <i>NCI Sponsored Study</i>	Abstract 4544 Poster 370 – Category: Genitourinary (Nonprostate) Cancer; Poster - Monday, 3 June, 1:15 PM - 4:15 PM; Hall A
	Circulating tumor cell (CTC) enumeration in patients (pts) with metastatic genitourinary (mGU) tumors treated in a phase I study of cabozantinib and nivolumab (CaboNivo) +/- ipilimumab (CaboNivolpi)	Abstract 4555 Poster 381 – Category: Genitourinary (Nonprostate) Cancer; Poster - Monday, 3 June, 1:15 PM - 4:15 PM; Hall A
	Correlates of overall survival (OS) in metastatic vs. primary uveal melanoma (UM) and results of a	Abstract 9506 – Oral: Category: Melanoma/Skin Cancers; Poster -

	randomized trial of cabozantinib (cabo) vs. chemotherapy (chemo) Alliance A091201 <i>NCI Sponsored Study</i>	Tuesday, 4 June, 11:45 AM - 11:57 AM; S406
Onivyde® (nal-IRI/liposomal irinotecan)	A multicenter phase Ib/II study of nalirinotecan, 5fluouracil and leucovorin in combination with nivolumab as second-line therapy for patients with advanced unresectable biliary tract cancer	Abstract TPS4154 Poster 252b – Category: Gastrointestinal (Noncolorectal) Cancer; Poster - Monday, 3 June, 8:00 AM - 11:00 AM; Hall A

### ABOUT IPSEN PRODUCTS

This press release mentions investigational uses of Ipsen products. Product indications and approvals for use vary by jurisdiction; please see SmPC/PI for full indications and safety information.

### ABOUT ONIVYDE® (irinotecan liposome injection)

ONIVYDE is an encapsulated formulation of irinotecan available as a 43 mg/10 mL single dose vial. This liposomal form is designed to increase length of tumor exposure to both irinotecan and its active metabolite, SN- 38.

On April 3, 2017, Ipsen completed the acquisition from Merrimack Pharmaceuticals of ONIVYDE and gained exclusive commercialization rights for the current and potential future indications for ONIVYDE in the US. Servier<sup>1</sup> is responsible for the development and commercialization of ONIVYDE outside of the U.S. and Taiwan under an exclusive licensing agreement with Ipsen Biopharm Ltd.

ONIVYDE is approved by the U.S. FDA 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.

<sup>1</sup> Servier is an international pharmaceutical company, governed by a non-profit foundation, with headquarters in the Paris metropolitan area.

### IMPORTANT SAFETY INFORMATION - UNITED STATES

#### BOXED WARNINGS: 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 5-FU and 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. Administer loperamide for late diarrhea of any severity. Administer atropine, if not contraindicated, for early diarrhea of any severity

#### CONTRAINDICATION

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

#### Warnings and Precautions

**Severe Neutropenia:** See Boxed WARNING. 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:** See Boxed WARNING. Severe and life-threatening late-onset (onset >24 hours after chemotherapy [9%]) and early-onset diarrhea (onset ≤24 hours after chemotherapy [3%], sometimes with other symptoms of cholinergic reaction) were observed

**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:** ONIVYDE can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during and for 1 month after ONIVYDE treatment

### Adverse Reactions

- The most common adverse reactions ( $\geq 20\%$ ) were diarrhea (59%), fatigue/asthenia (56%), vomiting (52%), nausea (51%), decreased appetite (44%), stomatitis (32%), and pyrexia (23%)
- The most common Grade 3/4 adverse reactions ( $\geq 10\%$ ) were diarrhea (13%), fatigue/asthenia (21%), and vomiting (11%)
- Adverse reactions led to permanent discontinuation of ONIVYDE in 11% of patients receiving ONIVYDE/5-FU/LV; The most frequent adverse reactions resulting in discontinuation of ONIVYDE were diarrhea, vomiting, and sepsis
- Dose reductions of ONIVYDE for adverse reactions occurred in 33% of patients receiving ONIVYDE/5-FU/LV; the most frequent adverse reactions requiring dose reductions were neutropenia, diarrhea, nausea, and anemia
- ONIVYDE was withheld or delayed for adverse reactions in 62% of patients receiving ONIVYDE/5-FU/LV; the most frequent adverse reactions requiring interruption or delays were neutropenia, diarrhea, fatigue, vomiting, and thrombocytopenia
- The most common laboratory abnormalities ( $\geq 20\%$ ) were anemia (97%), lymphopenia (81%), neutropenia (52%), increased ALT (51%), hypoalbuminemia (43%), thrombocytopenia (41%), hypomagnesemia (35%), hypokalemia (32%), hypocalcemia (32%), hypophosphatemia (29%), and hyponatremia (27%)

### 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

### Special Populations

- Pregnancy and Reproductive Potential: See WARNINGS & PRECAUTIONS. Advise males with female partners of reproductive potential to use condoms during and for 4 months after ONIVYDE treatment
- Lactation: Advise nursing women not to breastfeed during and for 1 month after ONIVYDE treatment

Please see full U.S. Prescribing Information for ONIVYDE®.

### ABOUT CABOMETYX® (cabozantinib)

CABOMETYX® is not marketed by Ipsen in the U.S.

CABOMETYX® 20mg, 40mg and 60mg film-coated unscored tablets

Active ingredient: Cabozantinib (S)-malate 20mg, 40mg and 60mg

Other components: Lactose

**Indications:** In the U.S., CABOMETYX tablets are approved for the treatment of patients with advanced RCC and for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.

CABOMETYX tablets are also approved in: the European Union, Norway, Iceland, Australia, Switzerland, South Korea, Canada, Brazil and Taiwan for the treatment of advanced RCC in adults who have received prior VEGF-targeted therapy; in the European Union for previously untreated intermediate- or poor-risk advanced RCC; in Canada for adult patients with advanced RCC who have received prior VEGF targeted therapy; and in the European Union, Norway and Iceland for HCC in adults who have previously been treated with sorafenib.

CABOMETYX is not indicated for previously untreated advanced HCC.

**Dosage and Administration:** The recommended dose of CABOMETYX® is 60 mg once daily. Treatment should continue until the patient is no longer clinically benefiting from therapy or until unacceptable toxicity occurs. Management of suspected adverse drug reactions may require temporary interruption and/or dose reduction of CABOMETYX® therapy. For dose modification, please refer to full SmPC. CABOMETYX® is for oral use. The tablets should be swallowed whole and not crushed. Patients should be instructed to not eat anything for at least 2 hours before through 1 hour after taking CABOMETYX®.

**Contraindications:** Hypersensitivity to the active substance or to any of the excipients listed in the SmPC.

### Special Warnings and Precautions For Use:

Monitor closely for toxicity during first 8 weeks of therapy. Events that generally have early onset include hypocalcemia, hypokalemia, thrombocytopenia, hypertension, palmar-plantar erythrodysesthesia syndrome (PPES), proteinuria, and

gastrointestinal (GI) events.

**Perforations and fistulas:** serious gastrointestinal perforations and fistulas, sometimes fatal, have been observed with cabozantinib. Patients with inflammatory bowel disease, GI tumor infiltration or complications from prior GI surgery should be evaluated prior to therapy and monitored; if perforation and unmanageable fistula occur, discontinue cabozantinib.

**Thromboembolic events:** use with caution in patients with a history of or risk factors for thromboembolism; discontinue if acute myocardial infarction (MI) or other significant arterial thromboembolic complication occurs.

**Hemorrhage:** not recommended for patients that have or are at risk of severe hemorrhage.

**Wound complications:** treatment should be stopped at least 28 days prior to scheduled surgery (including dental).

**Hypertension:** monitor blood pressure (BP); reduce with persistent hypertension and discontinue should uncontrolled hypertension or hypertensive crisis occur.

**Palmar-plantar erythrodysesthesia (PPES):** interrupt treatment if severe PPES occurs.

**Proteinuria:** discontinue in patients with nephrotic syndrome.

**Reversible posterior leukoencephalopathy syndrome (RPLS):** discontinue in patients with RPLS.

**QT interval prolongation:** use with caution in patients with a history of QT prolongation, those on antiarrhythmics or with pre-existing cardiac disease.

**Excipients:** do not use in patients with hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption.

**Drug Interactions:** Cabozantinib is a CYP3A4 substrate. Potent CYP3A4 inhibitors may result in an increase in cabozantinib plasma exposure (e.g. ritonavir, itraconazole, erythromycin, clarithromycin, grapefruit juice). Coadministration with CYP3A4 inducers may result in decreased cabozantinib plasma exposure (e.g. rifampicin, phenytoin, carbamazepine, phenobarbital, St John's Wort). Cabozantinib may increase the plasma concentration of P-glycoprotein substrates (e.g. fexofenadine, aliskiren, ambrisentan, dabigatran etexilate, digoxin, colchicine, maraviroc, posaconazole, ranolazine, saxagliptin, sitagliptin, talinolol, tolvaptan). MRP2 inhibitors may increase cabozantinib plasma concentrations (e.g. cyclosporine, efavirenz, emtricitabine). Bile salt sequestering agents may impact absorption or reabsorption resulting in potentially decreased cabozantinib exposure. No dose adjustment when co-administered with gastric pH modifying agents. A plasma protein displacement interaction may be possible with warfarin. INR values should be monitored in such a combination.

Women of childbearing potential/contraception in males and females: Ensure effective measures of contraception (oral contraceptive plus a barrier method) in male and female patients and their partners during therapy and for at least 4 months after treatment.

Pregnancy and lactation: CABOMETYX should not be used during pregnancy unless the clinical condition of the woman requires treatment. Lactation – discontinue breast-feeding during and for at least 4 months after completing treatment. Drive and use machines: Caution is recommended

#### Adverse Reactions:

The most common serious adverse reactions are hypertension, diarrhea, PPES, pulmonary embolism, fatigue and hypomagnesaemia. Very common (>1/10): anemia, lymphopenia neutropenia, thrombocytopenia, hypothyroidism, dehydration, decreased appetite, hyperglycemia, hypoglycemia, hypophosphatasemia, hypoalbuminemia, hypomagnesaemia, hyponatremia, hypokalemia, hyperkalemia, hypocalcemia, hyperbilirubinemia, peripheral sensory neuropathy, dysgeusia, headache, dizziness, hypertension, dysphonia, dyspnea, cough, diarrhea, nausea, vomiting, stomatitis, constipation, abdominal pain, dyspepsia, oral pain, dry mouth, PPES, dermatitis acneiform, rash, rash maculopapular, dry skin, alopecia, hair color change, pain in extremity, muscle spasms, arthralgia, proteinuria, fatigue, mucosal inflammation, asthenia, weight decreased, serum ALT, AST, and ALP increased, blood bilirubin increased, creatinine increased, triglycerides increased, white blood cell decreased, GGT increased, amylase increased, blood cholesterol increased, lipase increased. Common (>1/100 to <1/10): abscess, tinnitus, pulmonary embolism, pancreatitis, abdominal pain upper, gastro-esophageal reflux disease, hemorrhoids, pruritus, peripheral edema, wound complications. Uncommon (>1/1000 to <1/100): convulsion, anal fistula, hepatitis cholestatic, osteonecrosis of the jaw. Selected adverse events: GI perforation, fistulas, hemorrhage, RPLS.

Prescribers should consult the SPC in relation to other adverse reactions.

For more information, see the regularly updated registered product information on the European Medicine Agency [www.ema.europa.eu](http://www.ema.europa.eu)

ONIVYDE is a registered trademark of Ipsen Biopharm Limited.

XERMELO® is not marketed by Ipsen in the United States. The approved indications may vary by country. CABOMETYX® is marketed by Exelixis, Inc. in the United States. Ipsen has exclusive rights for the commercialization and further clinical development of CABOMETYX® outside of the United States and Japan.

#### ABOUT SOMATULINE® (lanreotide) Indications

SOMATULINE® DEPOT (lanreotide) is a somatostatin analog 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; and
- the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short acting somatostatin analog rescue therapy.

## IMPORTANT SAFETY INFORMATION

### Contraindications

- SOMATULINE DEPOT 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 DEPOT may reduce gallbladder motility and lead to gallstone formation.
  - Periodic monitoring may be needed.
  - If complications of cholelithiasis are suspected, discontinue SOMATULINE DEPOT and treat appropriately
- **Hypoglycemia or Hyperglycemia**
  - Patients treated with SOMATULINE DEPOT may experience hypoglycemia or hyperglycemia.
  - Blood glucose levels should be monitored when SOMATULINE DEPOT treatment is initiated, or when the dose is altered, and antidiabetic treatment should be adjusted accordingly.
- **Cardiovascular Abnormalities**
  - SOMATULINE DEPOT may decrease heart rate.
  - In patients without underlying cardiac disease, SOMATULINE DEPOT 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.

### Most Common Adverse Reactions

- **GEP-NETs:** Adverse reactions in >10% of patients who received SOMATULINE DEPOT were abdominal pain (34%), musculoskeletal pain (19%), vomiting (19%), headache (16%), injection site reaction (15%), hyperglycemia (14%), hypertension (14%), and cholelithiasis (14%).
- **Carcinoid Syndrome:** Adverse reactions occurring in the carcinoid syndrome trial were generally similar to those in the GEP-NET trial. Adverse reactions in ≥5% of patients who received SOMATULINE DEPOT and at least 5% greater than placebo were headache (12%), dizziness (7%) and muscle spasm (5%).

**Drug Interactions:** SOMATULINE DEPOT may decrease the absorption of cyclosporine (dosage adjustment may be needed); increase the absorption of bromocriptine; and require dosage adjustment for bradycardia-inducing drugs (e.g., beta-blockers).

### Special Populations

- Lactation: Advise women not to breastfeed during treatment and for 6 months after the last dose.
- To report SUSPECTED ADVERSE REACTIONS, contact Ipsen Biopharmaceuticals, Inc. at 1-855- 463-5127 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).
- Please click here for the full Prescribing Information and Patient Information.

### About Ipsen

Ipsen is a global specialty-driven biopharmaceutical group focused on innovation and specialty care. The group develops and commercializes innovative medicines in three key therapeutic areas – Oncology, Neuroscience and Rare Diseases. Its commitment to Oncology is exemplified through its growing portfolio of key therapies for prostate cancer, neuroendocrine tumors, renal cell carcinoma and pancreatic cancer. Ipsen also has a well-established Consumer Healthcare business. With total sales over €2.2 billion in 2018, Ipsen sells more than 20 drugs in over 115 countries, with a direct commercial presence in more than 30 countries. Ipsen's R&D is focused on its innovative and differentiated technological platforms located in the heart of the leading biotechnological and life sciences hubs (Paris-Saclay, France; Oxford, UK; Cambridge, US). The Group has about 5,700 employees worldwide. Ipsen is listed in Paris (Euronext: IPN) and in the United States through a Sponsored Level I American Depository Receipt program (ADR: IPSEY). For more information on Ipsen, visit [www.ipсен.com](http://www.ipсен.com).

### Forward Looking Statement

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

results obtained during pre-clinical trials will be confirmed subsequently during clinical trials, or that the results of clinical trials will be sufficient to demonstrate the safe and effective nature of the product concerned. There can be no guarantees a product will receive the necessary regulatory approvals or that the product will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Other risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the Group's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the Group's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions. The Group also depends on third parties to develop and market some of its products which could potentially generate substantial royalties; these partners could behave in such ways which could cause damage to the Group's activities and financial results. The Group cannot be certain that its partners will fulfil their obligations. It might be unable to obtain any benefit from those agreements. A default by any of the Group's partners could generate lower revenues than expected. Such situations could have a negative impact on the Group's business, financial position or performance. The Group expressly disclaims any obligation or undertaking to update or revise any forward-looking statements, targets or estimates contained in this press release to reflect any change in events, conditions, assumptions or circumstances on which any such statements are based, unless so required by applicable law. The Group's business is subject to the risk factors outlined in its registration documents filed with the French Autorité des Marchés Financiers. The risks and uncertainties set out are not exhaustive and the reader is advised to refer to the Group's 2018 Registration Document available on its website ([www.ipsen.com](http://www.ipsen.com)).

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