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Ipsen showcases studies at the ESMO 2019 Congress highlighting progress in new approaches for difficult-to-treat cancers

Presentations demonstrate promising advances for the treatment of advanced hepatocellular carcinoma, metastatic pancreatic cancer and neuroendocrine tumors

Paris (France), 26 September 2019 – Ipsen (Euronext: IPN; ADR: IPSEY) today announced that clinical trials with cabozantinib (Cabometyx[®]) in a variety of tumor types will be the subject of four presentations at the European Society for Medical Oncology (ESMO) Congress 2019 in Barcelona, Spain, from 27 September – 1 October 2019.

“At Ipsen, our mission is to accelerate the discovery, development and commercialization of new medicines. So, we’re delighted to be sharing new studies at ESMO that demonstrate potential advances in treatment for select cancers where few effective therapeutic options exist, so no patient is left behind,” said Dr. Alexandre Lebeaut, Ipsen’s Executive Vice President, R&D and Chief Scientific Officer.

Key studies including Ipsen medicines to be presented at ESMO 2019 Congress:

- **An overview** of the trial design of the pivotal Phase III (COSMIC-312) study of cabozantinib (C) in combination with atezolizumab vs sorafenib in patients with advanced hepatocellular carcinoma (aHCC) who have not received prior systemic anticancer therapy
- **A new QTWiST analysis** of the Phase III CELESTIAL study looking at the effect of second-line cabozantinib on health states for patients with aHCC after sorafenib

“While we’re making strides in our own research programs for other hard-to-treat-cancers, like small cell lung cancer and pancreatic adenocarcinoma, our complementary work with partners is catalyzing and broadening our efforts to fast-track new approaches for patients with significant unmet needs,” said Bartek Bednarz, Ipsen, Senior Vice-President, Oncology Franchise. “ESMO 2019 marks an important milestone for our partnership with Exelixis to further develop cabozantinib (Cabometyx[®]), as we have exceeded 100 joint cabozantinib-related abstracts accepted to medical congresses in our shared vision to progress the treatment for difficult-to-treat cancers.”

Follow Ipsen on Twitter via @IpsenGroup and keep up to date with ESMO 2019 Congress news and updates by using the hashtag #ESMO19.

Overview of key presentations featuring Ipsen medicines in development at the ESMO 2019

Congress:

Medicine	Abstract title	Abstract number/timing (CEST)
Cabometyx® (cabozantinib)	Effect of second-line cabozantinib on health states for patients with advanced hepatocellular carcinoma (aHCC) after sorafenib: QTWiST analysis from the CELESTIAL study	Abstract 754P – Poster Display – Sunday, 29 September, 12:00 PM; Hall 4
	Outcomes based on plasma biomarkers for the phase III CELESTIAL trial of cabozantinib (C) versus placebo (P) in advanced hepatocellular carcinoma (aHCC)	Abstract 678PD – Poster Discussion – Category: Gastrointestinal tumours, non-colorectal – Saturday, 28 September, 5:10 PM; Hall 7
	Prognostic and predictive factors from the phase III CELESTIAL trial of cabozantinib (C) versus placebo (P) in previously treated advanced hepatocellular carcinoma (aHCC)	Abstract 749P – Poster Display – Sunday, 29 September, 12:00 PM; Hall 4
	Phase III (COSMIC-312) study of cabozantinib (C) in combination with atezolizumab vs sorafenib in patients (pts) with advanced hepatocellular carcinoma (aHCC) who have not received prior systemic anticancer therapy	Abstract 833TiP – Poster Display – Sunday, 29 September, 12:00 PM; Hall 4
Onivyde® (irinotecan liposome injection) (nal-IRI/liposomal irinotecan)	Integrated population pharmacokinetic modelling of liposomal irinotecan in patients with various tumour types, including untreated metastatic pancreatic cancer (mPC)	Abstract 691P – Poster Display – Sunday, 29 September, 12:00 PM; Hall 4
Somatuline® Autogel® (lanreotide autogel/depot)	Baseline characteristics from CLARINET FORTE: Evaluating lanreotide autogel (LAN) 120 mg every 14 days in patients with progressive pancreatic or midgut neuroendocrine tumours during a standard first-line LAN regimen	Abstract 1388P – Poster Display – Sunday, 29 September, 12:00 PM; Hall 4

Key investigator sponsored study presentation featuring Ipsen medicine in development at the ESMO 2019 Congress:

Medicine	Abstract title	Abstract number/timing (CEST)
Onivyde® (irinotecan liposome injection) (nal-IRI/liposomal irinotecan)	Multicenter randomized phase II trial of 5-Fluorouracil/leucovorin (5-FU/LV) with or without liposomal irinotecan (nal-IRI) in metastatic biliary tract cancer (BTC) as second-line therapy after progression on gemcitabine plus cisplatin (GemCis): NIFTY trial	Abstract 829TiP – Poster Display – Sunday, 29 September, 12:00 PM; Hall 4

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, including Boxed Warnings.

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 U.S. Servier¹ 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.

¹Servier is an independent international pharmaceutical company, governed by a non-profit foundation, with headquarters in the Paris metropolitan area. For more information: www.servier.com

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/mm³ 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 ≥ 2 weeks prior to initiation of ONIVYDE[®]
- Avoid the use of strong CYP3A4 or UGT1A1 inhibitors, if possible, and discontinue strong CYP3A4 inhibitors ≥ 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, including BOXED WARNINGS, for ONIVYDE[®].

ONIVYDE[®] is a registered trademark of Ipsen Biopharm Limited.

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

CABOMETYX® is marketed by Exelixis, Inc. in the United States. Cabometyx (r) is a registered Trademark of Exelixis, Inc. Ipsen has exclusive rights for the commercialization and further clinical development of CABOMETYX® outside of the United States and Japan.

ABOUT SOMATULINE® (lanreotide)

Somatuline® Autogel® is made of the active substance lanreotide, which is a somatostatin analogue that inhibits the secretion of growth hormone and certain hormones secreted by the digestive system. The main indications of Somatuline® and Somatuline® Autogel® are:²

- The treatment of individuals with acromegaly when the circulating levels of Growth Hormone (GH) and/or Insulin-like Growth Factor-1 (IGF-1) remain abnormal after surgery and/or radiotherapy, or in patients who otherwise require medical treatment.
- The treatment of grade 1 and a subset of grade 2 (Ki-67 index up to 10%) gastroenteropancreatic neuroendocrine tumors (GEP-NETs) of midgut, pancreatic or unknown origin where hindgut sites of origin have been excluded, in adult patients with unresectable locally advanced or metastatic disease.
- The treatment of symptoms associated with neuroendocrine (particularly carcinoid) tumors.

IMPORTANT SAFETY INFORMATION

The detailed recommendations for the use of Somatuline® Autogel® are described in the Summary of Product Characteristics (SmPC), available [here](#).

² Somatuline® Autogel® SmPC. November 2018

Somatuline® and Autogel® are registered trademarks of Ipsen Pharma.

In the United States, Ipsen markets lanreotide as Somatuline® Depot.

INDICATIONS

SOMATULINE® DEPOT (lanreotide) is a somatostatin analog indicated for:

- the long-term treatment of patients with acromegaly who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option; the goal of treatment in acromegaly is to reduce growth hormone (GH) and insulin growth factor-1 (IGF-1) levels to normal;
- 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 shortacting 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 cardiac studies with acromegalic patients, the most common cardiac adverse reactions were sinus bradycardia, bradycardia, and hypertension.
 - 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.
- **Thyroid Function Abnormalities**
 - Slight decreases in thyroid function have been seen during treatment with lanreotide in acromegalic patients.
 - Thyroid function tests are recommended where clinically appropriate.
- **Monitoring/Laboratory Tests:** In acromegaly, serum GH and IGF-1 levels are useful markers of the disease and effectiveness of treatment.

Adverse Reactions

- Acromegaly: Adverse reactions in >5% of patients who received SOMATULINE DEPOT were diarrhea (37%), cholelithiasis (20%), abdominal pain (19%), nausea (11%), injection-site reactions (9%), constipation (8%), flatulence (7%), vomiting (7%), arthralgia (7%), headache (7%), and loose stools (6%).
- GEP-NETs: Adverse reactions >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 occurring 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.
- Moderate to Severe Renal and Hepatic Impairment: See full prescribing information for dosage adjustment in patients with acromegaly.

Please see full U.S. Prescribing Information, including SOMATULINE® DEPOT.

Somatuline Depot is a registered trademark of Ipsen Pharma S.A.S.

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.

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.ipсен.com).

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