

Ipsen to Present Data at ASCO GI 2018, Including New Post-Hoc Analyses from ONIVYDE® (irinotecan liposome injection) Phase 3 NAPOLI-1 Trial

– Review of NAPOLI-1 Data Evaluated Impact of Protocol-defined Dose Modifications Used to Manage Adverse Events on Overall Survival in Patients Treated with ONIVYDE® –

Basking Ridge, N.J., [January 17, 2018] – Ipsen Biopharmaceuticals, Inc., an affiliate of Ipsen, (Euronext: IPN; ADR: IPSEY), today announced that five new sub-analyses of the pivotal Phase 3 NAPOLI-1 trial will be presented at this year’s American Society of Clinical Oncology’s Gastrointestinal Cancer Symposium (ASCO GI) taking place in San Francisco, California, from January 18-20. The results of these post-hoc analyses may offer physicians insight into treatment strategies for metastatic pancreatic cancer patients who have progressed following gemcitabine-based therapy and are being treated with ONIVYDE® (irinotecan liposome injection) in combination with fluorouracil (5-FU) and leucovorin (LV). There will be seven ONIVYDE® poster presentations at this year’s conference. Three additional posters will be presented focused on neuroendocrine tumors (NETs) or Somatuline® Depot (lanreotide) Injection 120mg.

Wang-Gillam A, Hubner R, Mirakhur B, et al. Dose modifications of liposomal irinotecan (nal-IRI) + 5-fluorouracil/leucovorin (5-FU/LV) in NAPOLI-1: impact on efficacy. ASCO GI 2018 Abstract # 388; Friday, January 19, from 11:30AM PST – 1:00PM PST

In NAPOLI-1 (NCT01494506), a randomized phase 3 study in patients with metastatic pancreatic cancer previously treated with gemcitabine-based therapy, ONIVYDE®+5-FU/LV improved overall survival (OS; primary endpoint) vs 5-FU/LV (6.1 mos vs 4.2 mos; HR = 0.67, 95% CI 0.49–0.92; $P = 0.012$). In a post-hoc analysis examining the impact of protocol-defined dose reductions or delays used to manage adverse events (AEs) on overall survival (OS) in ONIVYDE®-treated patients, there was a numerical but not statistically significant difference in OS between patients who did have a dose reduction (patients = 34, OS = 9.3 mos) or dose delay (patients = 49, OS = 8.4 mos) vs. patients who did not require dose reductions (patients = 83, OS = 5.4 mos; HR = 0.66 [95% CI 0.43, 1.01]) or dose delays (patients = 68, OS = 5.6 mos; HR = 0.82 [95% CI 0.56, 1.23]). Adverse events (AE) seen in this post-hoc analysis was consistent with AEs reported in the NAPOLI-1 clinical trial.

In this post-hoc analysis, all patients who required a dose modification during the first 6 weeks of the trial were included. Dose reductions were defined as any reduction in dose from initial administered dose, and delays were defined as any delay in dosing greater than three days from the target dosing date. The study protocol allowed ≤ 2 dose reductions for ONIVYDE® and 5-FU/LV and for delays up to 3 weeks.

“Delays and dose reductions during the course of treatment frequently occurred in patients with metastatic pancreatic cancer who are generally fragile and weak from their illness,” **said lead investigator Andrea Wang-Gillam, MD, PhD, Associate Professor, Divisions of Hematology and Oncology at Washington University School of Medicine.** “These analyses provide physicians with additional insights on possible treatment strategies for this patient population.”

Wang-Gillam A, Hubner R, Mirakhur B, et al. Nomogram for predicting overall survival (OS) in patients (pts) treated with liposomal irinotecan (nal-IRI) ± 5-fluorouracil/leucovorin (5-FU/LV) in metastatic pancreatic ductal adenocarcinoma (mPDAC) previously treated with gemcitabine-based therapy in NAPOLI-1. ASCO GI 2018 Abstract # 459; Friday, January 19, from 11:30AM PST – 1:00PM PST

In a second post-hoc analysis of the NAPOLI-1 trial, researchers developed a diagram, or nomogram, representing the relationship between multiple variables to help predict OS in patients

with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy. Following both a univariate and multivariate analysis, eight predictive factors of OS were identified including ONIVYDE® + 5-FU/LV treatment, Karnofsky Performance Status (KPS), neutrophil-to-lymphocyte ratio (NLR), albumin level, baseline CA19-9, stage 4 at diagnosis, BMI, and presence of liver metastasis. The nomogram, which distinguishes between risk groups, and may aid in clinical decision-making, will be presented during poster session B (Board M6 – Abstract 459) on Friday, January 19 from 11:30AM-1:00PM PST.

“Ipsen is committed to continuing to understand the patients we serve, and it’s critical that we invest in ongoing research and additional studies that will better inform the treatment paradigm – this is particularly needed in pancreatic cancer where there are limited treatment options,” **said David Cox, Vice President, Global Medical Affairs – North America.**

Somatuline® Depot and NETs

Three additional Ipsen-sponsored studies have been accepted and will be presented as posters at this year’s ASCO GI conference, including a prospective analysis of the ELECT trial, which evaluates Somatuline® Depot’s impact on carcinoid syndrome in NET patients. The remaining two accepted abstracts were survey analyses focused on understanding the challenges and emotional burden NETs have on patients, with results revealing the need for additional informational resources for patients.

David Cox also said, “Identifying pain points in a patient’s treatment journey so that we can appropriately support them is a promise we deliver across Ipsen to provide high quality treatment options.”

**These post-hoc analyses of the NAPOLI-1 pivotal trial are not included in the U.S. prescribing information. See full ONIVYDE® prescribing information below.*

***The prospective analysis of the ELECT trial is not included in the U.S. prescribing information. See full Somatuline® Depot prescribing information below.*

About Pancreatic Cancer

Pancreatic cancer is a rare and deadly disease with about 55,440 people (29,200 men and 26,240 women) being diagnosed with pancreatic cancer in the United States alone.¹ More than half are diagnosed with metastatic disease, which has an overall 5-year survival rate of less than three percent¹, and often rapidly progresses during or shortly after receiving chemotherapy.² Pancreatic cancer accounts for about 3% of all cancers, and is the 3rd leading cause of cancer-related death in the United States, surpassing breast cancer.¹ It is expected to become the 2nd leading cause of cancer related death in the U.S. by the year 2030, surpassing colorectal cancer.^{1,3}

About Gastrointestinal and Pancreatic Neuroendocrine Tumors

Gastrointestinal and pancreatic neuroendocrine tumors, also known as gastroenteropancreatic neuroendocrine tumors (GEP-NETs), are a rare type of cancer. They are diagnosed in approximately 5 out of every 100,000 people in the U.S. There are an estimated 112,000 individuals currently living with neuroendocrine tumors in the U.S., and the incidence and prevalence of this type of cancer have risen 4-to-6 fold in the last 30 years. The average time until a patient with GEP-NETs is accurately diagnosed is at least 5 years; with more than 80% of patients seeing at least three doctors during their diagnosis. Because of this, most patients are diagnosed while in the advanced stages of the disease, which often leads to a poor prognosis. Additionally, many of the symptoms of GEP-NETs are gastrointestinal in nature, thus they can be easily misdiagnosed as Crohn’s disease or Irritable Bowel Syndrome (IBS).

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, SN38. 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. ONIVYDE is not indicated as a single agent for the treatment of patients with metastatic adenocarcinoma of the pancreas.

On April 3, 2017, Ipsen completed the acquisition from Merrimack Pharmaceuticals of ONIVYDE® (irinotecan liposome injection) for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy, in combination with fluorouracil and leucovorin. Ipsen gained exclusive commercialization rights for the current and potential future indications for ONIVYDE® in the U.S., as well as the current licensing agreements with Shire for commercialization rights ex-U.S. and PharmaEngine for Taiwan.

IMPORTANT SAFETY INFORMATION: ONIVYDE®

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.

WARNING: SEVERE NEUTROPENIA and SEVERE DIARRHEA

Fatal neutropenic sepsis occurred in 0.8% of patients receiving ONIVYDE®. Severe or lifethreatening 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/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

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 (≥20%) adverse reactions in which patients receiving ONIVYDE® /5-FU/LV experienced a ≥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 ≥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 ≥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 ≥ 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.

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/m² 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/m² 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 \leq 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](#) including Boxed WARNING for ONIVYDE®.

About SOMATULINE® DEPOT

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. Somatuline® Depot is also indicated for the treatment of carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.

IMPORTANT SAFETY INFORMATION: SOMATULINE® DEPOT

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.
- **Hypoglycemia or Hyperglycemia**
 - Pharmacological studies show that Somatuline® Depot, like somatostatin and other somatostatin analogs, inhibits the secretion of insulin and glucagon. 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 in the GEP-NET pivotal trial, 23% of Somatuline[®] Depot-treated patients had a heart rate of less than 60 bpm compared to 16% of placebo-treated patients. The incidence of bradycardia was similar in the treatment groups. Initiate appropriate medical management in patients with symptomatic bradycardia.
 - 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 occurring in greater than 10% of patients who received Somatuline[®] Depot in the GEP-NET trial 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 greater than 5% of patients who received Somatuline[®] Depot in the carcinoid syndrome trial and occurring 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.

Please click here for the full Somatuline[®] Depot [Prescribing Information](#) including [Patient Information](#).

About Ipsen in North America

Ipsen Biopharmaceuticals, Inc. is a U.S. affiliate of Ipsen (Euronext: IPN; ADR: IPSEY), a global specialty-driven biopharmaceutical group focused on innovation and specialty care. The U.S. head office is located in Basking Ridge, New Jersey, and its Canadian office, Ipsen Biopharmaceuticals Canada, Inc., an integrated business unit within North America, is located in Mississauga, Ontario. Additional research and development and manufacturing sites are located in Cambridge, Massachusetts, as part of Ipsen Bioscience, Inc., the Ipsen U.S. research and development center, which is focused on the discovery of potentially highly differentiated and competitive products in Oncology, Neurosciences and Rare Diseases. Ipsen North America employs more than 400 people and is dedicated to providing hope for the patients whose lives are challenged by difficult-to-treat diseases. At Ipsen, we focus our resources, investments and energy on discovering, developing and commercializing new therapeutic options for oncologic, neurologic and rare diseases. For more information on Ipsen in North America, please visit www.ipsenus.com or www.ipsen.ca.

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, Neurosciences 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 close to €1.6 billion in 2016, 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 5,100 employees worldwide. Ipsen is listed in Paris (Euronext: IPN) and in the United States through a Sponsored Level I American Depositary Receipt program (ADR: IPSEY). For more information on Ipsen, visit www.ipсен.com.

Forward Looking Statements

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 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. 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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Somatuline® DEPOT is a registered trademark of Ipsen Pharma S.A.S.

All other trademarks are the property of their respective owners.

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1 American Cancer Society. Cancer Facts and Figures 2017. Atlanta: American Cancer Society; 2018.
<https://www.cancer.org/cancer/pancreatic-cancer/about/key-statistics.html>

2 Ammermann et al. Decision Resources. Disease Landscape and & Forecast: Pancreatic Cancer. June 2016.

3 Rahib L, Smith BD, Aizenberg, et al. Projecting cancer incidence and deaths to 2030: the unexpected burden of thyroid, liver, and pancreas cancers in the United States. Cancer Res. 2014 Jun 1;74(11):2913-21. doi: 10.1158/0008-5472.CAN-14-0155.