

Ipsen to Acquire Oncology Assets from Merrimack Pharmaceuticals

- Transaction includes U.S. commercialization rights for ONIVYDE[®] for metastatic pancreatic cancer in adult patients¹
 - \$575 million cash at closing and additional potential payments for new indications
- Transaction bolsters Ipsen's growing oncology presence and leverages Oncology infrastructure in the U.S.

Paris (France), 9 January 2017 – Ipsen (Euronext: IPN; ADR: IPSEY) today announced that it has entered into a definitive agreement to acquire global oncology assets from Merrimack Pharmaceuticals (NASDAQ: MACK), including its key marketed product 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. Under the terms of the agreement, Ipsen will gain exclusive commercialization rights for the current and potential future ONIVYDE indications in the U.S., as well as the current licensing agreements with Shire for commercialization rights ex-U.S. and PharmaEngine for Taiwan. The transaction also includes Merrimack's commercial and manufacturing infrastructure, and generic doxorubicin HCI liposome injection.

The transaction represents a unique opportunity and a strong strategic fit for Ipsen. ONIVYDE is a clinically differentiated and FDA-approved product for patients with high unmet medical needs. The transaction secures a marketed, wholly-owned asset with current U.S. revenues and significant revenue growth projections, based on solid clinical data and potential approvals in additional indications already in clinical development. Furthermore, there are significant commercial synergies to be realized by integrating the ONIVYDE franchise with the existing Ipsen U.S. oncology commercial infrastructure, which has strong expertise and a proven track record with Somatuline[®]. As a result, this transaction strengthens Ipsen's Oncology franchise and accelerates both its near- and long-term growth trajectory and profitability.

David Meek, CEO of Ipsen, commented, "The acquisition of ONIVYDE represents a compelling strategic opportunity to further strengthen Ipsen's oncology portfolio while leveraging our U.S. infrastructure and creating meaningful potential incremental growth and profitability. Pancreatic cancer is now the third leading cause of cancer-related deaths. It is an area that has had many drug failures and very few FDA approvals over the past two decades. For the tens of thousands of patients living with pancreatic cancer in the U.S. who have received prior treatment with

¹ Onivyde[®] is indicated in combination with fuorouracil and leucovorin after disease progression following gemcitabine-based therapy



gemcitabine, ONIVYDE represents an important, differentiated innovation, given its proven overall survival benefit in an area of high unmet medical need with few approved therapies."

"ONIVYDE is a landmark, recently approved therapeutic option for metastatic pancreatic cancer. Since the launch in the fourth quarter of 2015, many patients have already benefitted from ONIVYDE." said **Cynthia Schwalm, Executive Vice President, North America Commercial Operations, Ipsen**. "Based on our track record of successfully bringing oncology products to patients, we are confident in our ability to leverage our operational and clinical development capabilities, and experienced commercial and medical affairs teams to ensure eligible patients have access to ONIVYDE in the U.S."

Ipsen will be responsible for advancing the ongoing ONIVYDE clinical development program, which includes a Phase 2 trial in first-line previously untreated metastatic pancreatic cancer, a Phase 2/3 trial in relapsed small-cell lung cancer, and a Phase 1 pilot trial in breast cancer.

Under the terms of the agreement, Ipsen will pay \$575 million cash at closing plus up to \$450 million upon the approval of potential additional indications for ONIVYDE in the U.S. The transaction will be fully financed by Ipsen's existing cash and lines of credit. The deal should be dilutive in 2017 and accretive from 2018 onwards both in operating margin and EPS. The transaction, which is subject to customary closing conditions, including governmental regulatory clearances, and a vote by Merrimack shareholders, is expected to close by the end of the first quarter of 2017.

Ipsen was advised on this transaction by MTS Health Partners, LP and Dechert LLP.

Conference Call

Ipsen will host a conference call and web conference (available at <u>www.ipsen.com</u>) today to discuss this announcement. Participants should dial in approximately 5 to 10 minutes prior to the start. No reservation is required to participate in the conference call.

Date: 9 January, 2017 Time: 2:30pm CET/ 8:30am EST France and continental Europe +33 (0)1 7099 3208 UK +44 (0)20 7162 0077 United States +1 646 851 2407 Conference ID: 961094

A replay will be available for seven days on Ipsen's website: <u>www.ipsen.com/</u> France and continental Europe +33 (0)1 7099 3529 UK +44 (0)20 7031 4064 United States +1 954 334 0342 Conference ID: 961094

About Pancreatic Cancer

Pancreatic cancer is a rare and deadly disease with approximately 338,000 new patients diagnosed globally each year, approximately 50,000 of which are in the United States². More

² American Cancer Society. Cancer Facts and Figures 2016. Atlanta: American Cancer Society; 2016



than half are diagnosed with metastatic disease who have an overall 5-year survival rate of two percent², and often rapidly progress during or shortly after receiving chemotherapy³. Pancreatic cancer is the 3rd leading cause of cancer-related death in the United States surpassing breast cancer.² It is expected to become the 2nd leading cause of cancer-related death in the US by the year 2030, surpassing colorectal cancer.²

About ONIVYDE®

ONIVYDE[®] is a unique encapsulation formulation of irinotecan in a long-circulating liposomal form designed to increase the length of tumor exposure to irinotecan and its active metabolite SN-38.

In the pivotal Phase 3 NAPOLI-1 study, ONIVYDE with fluorouracil and folinic acid demonstrated a statistically significant improvement of overall survival in adult patients with metastatic adenocarcinoma of the pancreas who have progressed following gemcitabine-based therapy³. Gemcitabine, both as monotherapy as well as in combination, is commonly used in the first-line treatment of locally advanced and/or metastatic pancreatic adenocarcinoma, as well as in the adjuvant (treatment after surgery) and neo-adjuvant (treatment before surgery) settings⁴.

Ipsen will market the product in the United States where ONIVYDE received US Food and Drug Administration (FDA) approval in October 2015 in combination with fluorouracil and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas who have progressed following treatment with gemcitabine-based therapy.

Shire is responsible for the development and commercialization of ONIVYDE outside of the United States and Taiwan under an exclusive licensing agreement with Merrimack Pharmaceuticals, Inc. In October 2016, the European Commission (EC) granted Marketing Authorization of ONIVYDE for the treatment of metastatic adenocarcinoma of the pancreas, in combination with 5-fluorouracil (5-FU) and leucovorin (LV), in adult patients who have progressed following gemcitabine-based therapy.

The ONIVYDE product license was granted to PharmaEngine in March 2016 for commercialization rights in Taiwan.

Licenses outside the U.S. will be transferred to Ipsen.

About Generic Doxorubicin HCI Liposome Injection

Generic doxorubicin HCI Liposome Injection is currently being evaluated by the U.S. Food and Drug Administration (FDA) for the potential treatment of ovarian cancer, multiple myeloma and Kaposi's sarcoma. Teva retains the worldwide commercial rights for this product, and Ipsen will be eligible to receive milestones and shared profits from potential sales.

About Ipsen in North America

Ipsen Biopharmaceuticals, Inc. is the US affiliate of Ipsen, a global specialty driven pharmaceutical group. The US head office is located in Basking Ridge, New Jersey. Ipsen

³ Ammermann et al. Decision Resources. Disease Landscape and & Forecast: Pancreatic Cancer. June 2016.

⁴ Wang-Gillam A, et al. Nanoliposomal irinotecan with fluorouracil and folinic acid in metastatic pancreatic cancer after previous gemcitabine-based therapy (NAPOLI-1): a global, randomised, open-label, phase 3 trial. The Lancet. 2016; 387(10018):545-557.



Biopharmaceuticals Canada, Inc. is an integrated business unit within North America and has its head office located in Mississauga, Ontario. Ipsen Bioscience, Inc., the Ipsen US research and development center focused on peptide research in oncology and endocrinology, is located in Cambridge, Massachusetts. At Ipsen Bioscience, we focus on creating a highly cooperative and passionate R&D organization through partnerships, innovation, and continuous learning to effectively deliver new treatments for patients. At Ipsen Biopharmaceuticals, we focus our resources, investments, and energy on discovering, developing, and commercializing new therapeutic options for oncologic, neurologic, and endocrine diseases. For more information on Ipsen in North America, please visit <u>www.ipsenus.com</u> or <u>www.ipsen.ca</u>.

About Ipsen in Oncology

Ipsen focuses its efforts in fighting cancers such as prostate cancer or those with high unmet medical needs such as bladder cancer, neuroendocrine tumors, kidney cancer, pancreatic cancer and other niche oncology diseases. Our ambition is to offer new therapeutic options to patients and caregivers in their treatment journeys. Ipsen has a continuous commitment in innovative treatment development in oncology through an open innovation approach and using differentiated technological platforms notably in peptides. Moreover Ipsen has built scientific partnerships with trusted academic institutions, leading pharmaceutical and biotech companies and work with today's top researchers and clinicians. We thus develop effective and innovative therapeutic solutions to improve treatment outcomes for patients and to support healthcare professionals in their daily practice.

About Ipsen

Ipsen is a global specialty-driven pharmaceutical group with total sales exceeding €1.4 billion in 2015. 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 neuro-endocrine tumors, prostate cancer, bladder cancer and renal 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 2015, R&D expenditures neared €193 million. The Group has more than 4,600 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 <u>www.ipsen.com</u>.

Ipsen 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 forwardlooking 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 2015 Registration Document available on its website (www.ipsen.com).

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