PRESS RELEASE

European Commission approves Ipsen's Cabometyx® (cabozantinib) for the first-line treatment of adults with intermediate- or poor-risk advanced renal cell carcinoma

Paris, France, 17 May 2018 – Ipsen (Euronext: IPN; ADR: IPSEY) today announced that the European Commission (EC) has approved Cabometyx® (cabozantinib) 20, 40, 60 mg for the first-line treatment of adults with intermediate- or poor-risk advanced renal cell carcinoma (aRCC). This approval allows for the marketing of Cabometyx® (cabozantinib) in this indication in all 28 member states of the European Union, Norway and Iceland.

"Today's EC approval is a step forward for advanced kidney cancer patients in Europe who will be able to access a new oral first-line treatment option that offers significant improvement over the standard of care," said **Harout Semerjian, Executive Vice President, Chief Commercial Officer, Ipsen.** *"Ipsen remains committed to improving patients' lives by continuing to develop new therapies and expanding the potential of Cabometyx® across different indications."*

Giuseppe Procopio, M.D., Head of the Genitourinary Unit at Fondazione Istituto Nazionale Tumori Milan, stated: *"The value of treatment with Cabometyx® has been corroborated by the data generated in clinical trials, and since 2016 physicians have also witnessed the potential of it when treating patients following VEGF-targeted therapy. For both of these reasons, physicians will be pleased to soon have access to this new first-line treatment option for intermediate- or poor-risk advanced RCC patients."*

Today's decision is based on the CABOSUN trial, which demonstrated that cabozantinib significantly prolongs progression-free survival (PFS) compared to sunitinib in treatment-naive aRCC patients with intermediate- or poor-risk. Cabozantinib is the first and only monotherapy to demonstrate superior clinical efficacy over sunitinib in treatment-naïve aRCC patients with intermediate- or poor-risk.

The detailed recommendations for the use of this product are described in the Summary of Product Characteristics (SmPC), available here (https://cabometyx.eu/).

About the CABOSUN study

On May 23, 2016, Exelixis announced that CABOSUN met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in PFS compared with sunitinib in patients with intermediate- or poor-risk aRCC per IMDC (International Metastatic RCC Carcinoma Database Consortium) criteria as determined by investigator assessment. CABOSUN was conducted by The Alliance for Clinical Trials in Oncology as part of Exelixis' collaboration with the NCI-CTEP. These results were first presented by Dr. Toni Choueiri at the meeting of the European Society for Medical Oncology (ESMO) 2016, and published in the Journal of Clinical Oncology (Choueiri, JCO, 2018).[i]

On June 19 2017 Exelixis announced that the analysis of the review by a blinded independent radiology review committee (IRC) has confirmed the primary efficacy endpoint results of investigator-assessed progression-free survival (PFS) from the CABOSUN randomized phase 2 trial of cabozantinib as compared with sunitinib in patients with previously untreated advanced renal cell carcinoma (RCC) with intermediate- or poor-risk disease per the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) criteria. Per the IRC analysis, cabozantinib demonstrated a clinically meaningful and statistically significant reduction in the rate of disease progression or death as measured by PFS. The incidence of adverse events (any grade) and the incidence of grade 3 or 4 adverse events between cabozantinib and sunitinib were comparable.

CABOSUN is a randomized, open-label, active-controlled phase II trial that enrolled 157 patients with aRCC determined to be intermediate- or poor-risk per IMDC criteria. Patients were randomized 1:1 to receive cabozantinib (60 mg once daily) or sunitinib (50 mg once daily, four weeks on followed by two weeks off). The primary endpoint was PFS. Secondary endpoints included overall survival and objective response rate. Eligible patients were required to have locally advanced or metastatic clear-cell RCC, ECOG performance status 0-2, and had to be intermediate- or poor-risk per IMDC criteria (Heng, JCO, 2009).[ii] Prior systemic treatment for RCC was not permitted.

About advanced Renal Cell Carcinoma

With the incidence predicted to rise 22% by 2020, renal cell carcinoma (RCC) threatens to become one of the fastest growing cancers in the world.[iii] Targeted therapies including tyrosine kinase inhibitors (TKIs) of the VEGF receptor (VEGFR) introduced a decade ago, significantly transformed the treatment landscape of aRCC.[iv]

The American Cancer Society's 2017 statistics cite kidney cancer as one of the top ten most commonly diagnosed forms of cancer among both men and women in the U.S.[v] Clear cell RCC is the most common type of kidney cancer in adults.[vi] If detected in its early stages, the five-year survival rate for RCC is high. For patients with advanced- or late-stage metastatic RCC, however,

the five-year survival rate is only 12% with no identified cure for the disease.[vii] Approximately 30,000 patients in the U.S. and 68,000 globally require treatment.[viii]

The majority of clear cell RCC tumors have lower than normal levels of a protein called von Hippel-Lindau, which leads to higher levels of MET, AXL, and VEGF.[ix-x] These proteins promote tumor angiogenesis (blood vessel growth), growth, invasiveness, and metastasis.[xi, xii, xiii, xiv] MET and AXL may provide escape pathways that drive resistance to VEGFR inhibitors. [xii - xiv]

About CABOMETYX® (cabozantinib)
Cabometyx® is an oral small molecule inhibitor of receptors, including VEGFR, MET, AXL and RET. In preclinical models, cabozantinib has been shown to inhibit the activity of these receptors, which are involved in normal cellular function and pathologic processes such as tumor angiogenesis, invasiveness, metastasis and drug resistance.

In February of 2016, Exelixis and Ipsen jointly announced an exclusive licensing agreement for the commercialization and further development of cabozantinib indications outside of the United States, Canada and Japan. This agreement was amended in December of 2016 to include commercialization rights for Ipsen in Canada. On April 25, 2016, the FDA approved Cabometyx® tablets for the treatment of patients with advanced RCC who have received prior anti-angiogenic therapy and on September 9, 2016, the European Commission approved Cabometyx® tablets for the treatment of advanced RCC in adults who have received prior vascular endothelial growth factor (VEGF)-targeted therapy in the European Union, Norway and Iceland. Cabometyx® is available in 20 mg, 40 mg or 60 mg doses. The recommended dose is 60 mg orally, once daily.

On December 19, 2017, Exelixis received approval from the FDA for Cabometyx® for the expanded indication of treatment of advanced RCC.

On May 17, 2018, Ipsen announced that the European Commission approved Cabometyx® for the first-line treatment of adults with intermediate- or poor-risk advanced renal cell carcinomain the European Union, Norway and Iceland.

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 €1.9 billion in 2017, 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 5,400 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.ipsen.com.

Ipsen Forward Looking Statement

The forward-looking statements, objectives and targets contained herein are based on the Group's management strategy, current views and assumptions. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated herein. All of the above risks could affect the Group's future ability to achieve its financial targets, which were set assuming reasonable macroeconomic conditions based on the information available today. Use of the words "believes," "anticipates" and "expects" and similar expressions are intended to identify forward-looking statements, including the Group's expectations regarding future events, including regulatory filings and determinations. Moreover, the targets described in this document were prepared without taking into account external growth assumptions and potential future acquisitions, which may alter these parameters. These objectives are based on data and assumptions regarded as reasonable by the Group. These targets depend on conditions or facts likely to happen in the future, and not exclusively on historical data. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties, notably the fact that a promising product in early development phase or clinical trial may end up never being launched on the market or reaching its commercial targets, notably for regulatory or competition reasons. The Group must face or might face competition from generic products that might translate into a loss of market share. Furthermore, the Research and Development process involves several stages each of which involves the substantial risk that the Group may fail to achieve its objectives and be forced to abandon its efforts with regards to a product in which it has invested significant sums. Therefore, the Group cannot be certain that 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 2017 Registration Document available on its website (www.ipsen.com).

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