



## Exelixis and Ipsen Amend Exclusive Licensing Agreement for the Commercialization and Development of Cabozantinib to Include Canada

December 21, 2016

**-- Amendment enhances productive year with CABOMETYX™ regulatory approvals and commercial launches in the United States and European Union**

**-- Exelixis to receive \$10 million upfront payment, with subsequent regulatory and commercial milestones**

PARIS & SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Dec. 21, 2016-- Exelixis, Inc. (NASDAQ:EXEL) and Ipsen (Euronext:IPN; ADR:IPSEY) today jointly announced an amendment to the exclusive collaboration and licensing agreement for the commercialization and continued development of cabozantinib, to include commercialization rights in Canada for Ipsen where Ipsen has an established business (Mississauga, Ontario). Signed in February 2016, the original agreement gave Ipsen exclusive commercialization rights for current and potential future cabozantinib indications outside of the United States, Canada and Japan. Following the amendment, Exelixis maintains exclusive rights for cabozantinib in the United States and Japan, and is continuing discussions with potential partners for commercial rights in Japan.

Under the terms of the amendment, Exelixis will receive a \$10 million upfront payment. Exelixis is eligible to receive regulatory milestones, for the approvals of cabozantinib in Canada for advanced renal cell carcinoma (RCC) after prior treatment, for first-line RCC, and advanced hepatocellular carcinoma (HCC), as well as additional regulatory milestones for potential further indications. In line with the prior transaction between the parties, the agreement also includes commercial milestones and provides for Exelixis to receive tiered royalties on Ipsen's net sales of cabozantinib in Canada.

"Exelixis and Ipsen have made significant progress together since signing our collaboration and licensing agreement in February, and considering the substantial business resources that Ipsen has in Canada, amending the terms to grant Ipsen Canadian rights is a natural next step," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "Over the past nine months, CABOMETYX received regulatory approval for advanced RCC in the United States as well as the European Union, where Ipsen recently began launching the product. Our collaboration with Ipsen is strong, and we look forward to continued progress as they pursue approval and commercialization in Canada."

David Meek, Chief Executive Officer of Ipsen, said, "Gaining commercial rights for CABOMETYX in Canada expands our geographic footprint and strengthens our Oncology franchise in North America, one of our key geographic regions and main drivers of growth. This announcement follows numerous advancements in the CABOMETYX program, including the recent approval in Europe. We are now focused on a successful European launch and are pleased to offer advanced renal cell carcinoma patients a new treatment option supported by a strong clinical profile. We look forward to continue working with our partner Exelixis to advance the cabozantinib program."

CABOMETYX was approved in the European Union (EU) on September 9, 2016 for the treatment of RCC in adults following prior vascular endothelial growth factor (VEGF)-targeted therapy. Ipsen is currently initiating the launch of CABOMETYX in the EU. The regulatory filing in Canada is expected in 2017, with regulatory approval anticipated in early 2018.

### **About CABOMETYX™**

CABOMETYX is the tablet formulation of cabozantinib. Its targets include MET, AXL and VEGFR-1, -2 and -3. 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.

CABOMETYX is available in 20 mg, 40 mg or 60 mg doses. The recommended dose is 60 mg orally, once daily.

On April 25, 2016, the FDA approved CABOMETYX tablets for the treatment of patients with advanced renal cell carcinoma who have received prior anti-angiogenic therapy. On September 9, 2016, the European Commission approved CABOMETYX tablets for the treatment of advanced renal cell carcinoma in adults who have received prior vascular endothelial growth factor (VEGF)-targeted therapy in the European Union, Norway and Iceland.

### **About Exelixis' Exclusive Licensing Agreement with Ipsen**

In February 2016, Exelixis granted Ipsen exclusive commercialization rights for current and potential future cabozantinib indications outside of the United States, Canada and Japan. On 20 December 2016, Exelixis granted Ipsen the commercial and development rights for cabozantinib in Canada. As provided in their agreement, Exelixis and Ipsen are also collaborating on the development of cabozantinib for current and potential future indications.

### **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 prostate cancer, bladder cancer and neuro-endocrine tumors. 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 expenditure totaled close to €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 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 trade on the over-the-counter market in the United States under the symbol IPSEY. For more information on Ipsen, visit [www.ipсен.com](http://www.ipсен.com).

## About Exelixis

Exelixis, Inc. (Nasdaq:EXEL) is a biopharmaceutical company committed to the discovery, development and commercialization of new medicines with the potential to improve care and outcomes for people with cancer. Since its founding in 1994, three medicines discovered at Exelixis have progressed through clinical development to receive regulatory approval. Currently, Exelixis is focused on advancing cabozantinib, an inhibitor of multiple tyrosine kinases including MET, AXL and VEGF receptors, which has shown clinical anti-tumor activity in more than 20 forms of cancer and is the subject of a broad clinical development program. Two separate formulations of cabozantinib have received regulatory approval to treat certain forms of kidney and thyroid cancer and are marketed for those purposes as CABOMETYX™ tablets (U.S. and EU) and COMETRIQ® capsules (U.S. and EU), respectively. Another Exelixis-discovered compound, COTELLIC® (cobimetinib), a selective inhibitor of MEK, has been approved in major territories including the United States and European Union, and is being evaluated for further potential indications by Roche and Genentech (a member of the Roche Group) under a collaboration with Exelixis. For more information on Exelixis, please visit [www.exelixis.com](http://www.exelixis.com) or follow @ExelixisInc on Twitter.

## 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 favourable 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 guarantee 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 2014 Registration Document available on its website ([www.ipсен.com](http://www.ipсен.com)).

## Exelixis – Forward Looking Statement

This press release contains forward-looking statements, including, without limitation, statements related to: Exelixis' receipt of a \$10 million upfront payment; Exelixis' eligibility to receive regulatory milestones for the approvals of cabozantinib in Canada for advanced RCC after prior treatment, for first-line RCC, and advanced HCC, as well as additional regulatory milestones for potential further indications; the potential receipt of tiered royalties on Ipsen's net sales of cabozantinib in Canada; Ipsen's continued progress toward the pursuit of approval and commercialization of cabozantinib in Canada; the expectation that the regulatory filing in Canada for cabozantinib in advanced RCC will be in 2017, with regulatory approval anticipated in early 2018; Exelixis' commitment to the discovery, development and commercialization of new medicines with the potential to improve care and outcomes for people with cancer; Exelixis' focus on advancing cabozantinib; and the continued development of cobimetinib. Words such as "will," "eligible," "potential," "further," "look forward," "expected," "anticipated," "committed," "focused," or other similar expressions identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are based upon Exelixis' current plans, assumptions, beliefs, expectations, estimates and projections. Forward-looking statements involve risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in the forward-looking statements as a result of these risks and uncertainties, which include, without limitation: the complexities and challenges associated with regulatory review and approval processes; Exelixis' dependence on its relationship with Ipsen, including, the level of Ipsen's investment in the resources necessary to successfully commercialize cabozantinib in Canada and other territories where it is approved; the degree of market acceptance of CABOMETYX and the availability of coverage and reimbursement for CABOMETYX; the risk that unanticipated developments could adversely affect the commercialization of CABOMETYX; Exelixis' ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; risks related to the potential failure of cabozantinib to demonstrate safety and efficacy in clinical testing; Exelixis' dependence on its relationship with Genentech/Roche with respect to cobimetinib and Exelixis' ability to maintain its rights under the collaboration; Exelixis' dependence on third-party vendors; Exelixis' ability to protect the company's intellectual property rights; market competition; changes in economic and business conditions, and

other factors discussed under the caption "Risk Factors" in Exelixis' quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 3, 2016, and in Exelixis' future filings with the SEC. The forward-looking statements made in this press release speak only as of the date of this press release. Exelixis expressly disclaims any duty, obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Exelixis' expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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Source: Exelixis, Inc.

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