# Exelixis and Its Partner Ipsen Announce Positive Overall Survival Results from Subgroup Analyses of Phase 3 Trial of CABOMETYX™ (cabozantinib) Tablets in Advanced Renal Cell Carcinoma at 2016 ASCO Annual Meeting

June 6, 2016

***- Additional data from pivotal METEOR trial underscore clinically meaningful benefit of CABOMETYX across subgroups of patients -***

SOUTH SAN FRANCISCO, Calif. & PARIS--(BUSINESS WIRE)--Jun. 6, 2016-- Exelixis, Inc. (NASDAQ:EXEL) and Ipsen (Euronext: IPN; ADR: IPSEY) today announced the presentation of positive data from subgroup analyses of the pivotal METEOR trial comparing CABOMETYX™ (cabozantinib) tablets with everolimus in 658 patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy. The data will be presented in two posters today at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting, which is being held June 3-7 in Chicago, by Bernard Escudier, M.D., chair, Genitourinary Oncology Committee, Institut Gustave Roussy and Thomas Powles, M.D., clinical professor of genitourinary oncology, Barts Cancer Institute. The findings demonstrate that benefits of CABOMETYX in progression-free survival (PFS) and overall survival (OS) were independent of the presence of bone metastases, prior anti-PD-1/PD-L1 therapy, and the type of prior vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) therapy.

“These additional analyses demonstrate the value of CABOMETYX for advanced kidney cancer, showing consistent improvement in PFS and OS across multiple subgroups of patients in the METEOR trial,” said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. “We are dedicated to exploring the full potential of CABOMETYX to help as many patients as possible.”

In the first of the two presentations, treatment with CABOMETYX was associated with improved PFS and OS in patients who had bone metastases at baseline (n=142). Median PFS was 7.4 months with CABOMETYX versus 2.7 months with everolimus (HR=0.33, 95% CI 0.21-0.51), and median OS was 20.1 months versus 12.1 months, respectively (HR=0.54, 95% CI 0.34-0.84).

For patients who had both bone and visceral metastases (n=112), median PFS was 5.6 months with CABOMETYX and 1.9 months with everolimus (HR=0.26, 95% CI 0.16-0.43). Median OS was 20.1 months versus 10.7 months, respectively (HR=0.45, 95% CI 0.28-0.72). The safety profile of CABOMETYX for the subgroup with bone metastases was consistent with that of the overall METEOR trial.

“Patients whose kidney cancer has spread to their bones traditionally have a poorer prognosis and worse treatment outcomes compared with those who do not have bone involvement,” said Dr. Escudier. “CABOMETYX demonstrated a clinically meaningful benefit for those with bone metastases, which is encouraging for physicians and patients who are seeking additional therapeutic options.”

In the second presentation, outcomes were evaluated based on the prior therapy patients had received before entering the METEOR trial. OS and PFS benefits were consistent across all subgroups evaluated (see table below), including number of prior VEGFR TKIs (one or more than one), specific prior VEGFR TKI (sunitinib or pazopanib) in patients who had only one prior VEGFR TKI therapy, and prior treatment with anti-PD-1/PD-L1 therapies. Adverse events in the treatment subgroups were similar to those in the overall study population and were managed with dose reductions.

**Table. OS and PFS in METEOR by Subgroup**

| Subgroup | n | Median OS (months) | | OS Hazard Ratio (95% CI) | Median PFS (months) | | PFS Hazard Ratio (95% CI) |
|---|---|---|---|---|---|---|---|
| | | CABOMETYX | Everolimus | | CABOMETYX | Everolimus | |
| **Number of prior VEGFR TKIs** | | | | | | | |
| **1** | 464 | 21.4 | 16.5 | 0.65 (0.50-0.85) | 7.4 | 3.8 | 0.52 (0.41-0.66) |
| **≥2** | 194 | 20.8 | 17.2 | 0.73 (0.48-1.10) | 7.4 | 4.0 | 0.51 (0.35-0.74) |
| **Only prior VEGFR TKI** | | | | | | | |
| **Sunitinib** | 267 | 21.4 | 16.5 | 0.66 (0.47-0.93) | 9.1 | 3.7 | 0.43 (0.32-0.59) |
| **Pazopanib** | 171 | 22.0 | 17.5 | 0.66 (0.42-1.04) | 7.4 | 5.1 | 0.67 (0.45-0.99) |
| **Prior anti-PD-1/PD-L1 therapy** | | | | | | | |
| **No** | 626 | 21.4 | 16.5 | 0.68 (0.54-0.85) | 7.4 | 3.9 | 0.54 (0.44-0.66) |
| **Yes** | 32 | Not estimable | 16.3 | 0.56 (0.21-1.52) | Not estimable | 4.1 | 0.22 (0.07-0.65) |

“These findings demonstrate that the benefit of CABOMETYX for patients was robust and consistent regardless of prior treatment, location and extent of tumor metastases,” said Marc de Garidel, Chairman and CEO, Ipsen.

On April 25, 2016 CABOMETYX was approved by the U.S. Food and Drug Administration (FDA) for the treatment of patients with advanced RCC who have received prior anti-angiogenic therapy. CABOMETYX, which was granted Fast Track and Breakthrough Therapy designations by the FDA, is the first approved single agent therapy to demonstrate, in a phase 3 trial for patients with advanced RCC, robust and clinically meaningful improvements in all three key efficacy parameters — OS, PFS and objective response rate.

Please see Important Safety Information below and full U.S. prescribing information for CABOMETYX™ (cabozantinib) tablets at https://cabometyx.com/downloads/cabometyxuspi.pdf

**About the METEOR Phase 3 Pivotal Trial**

METEOR was an open-label, event-driven trial of 658 patients with advanced renal cell carcinoma who had failed at least one prior VEGFR TKI therapy. The primary endpoint was PFS in the first 375 patients treated. Secondary endpoints included OS and objective response rate in all enrolled patients. The trial was conducted at approximately 200 sites in 26 countries, and enrollment was weighted toward Western Europe, North America, and Australia. Patients were randomized 1:1 to receive 60 mg of CABOMETYX daily or 10 mg of everolimus daily and were stratified based on the number of prior VEGFR TKI therapies received and on MSKCC risk criteria. No cross-over was allowed between the study arms.

METEOR met its primary endpoint of significantly improving PFS. Compared with everolimus, CABOMETYX was associated with a 42 percent reduction in the rate of disease progression or death. Median PFS for CABOMETYX was 7.4 months versus 3.8 months for everolimus (HR=0.58, 95% CI 0.45-0.74, P<0.0001). CABOMETYX also significantly improved the objective response rate compared with everolimus (P<0.0001). These data were presented at the European Cancer Congress in September 2015 and published in *The New England Journal of Medicine*.[1]

CABOMETYX also demonstrated a statistically significant and clinically meaningful increase in OS in the METEOR trial. Compared with everolimus, CABOMETYX was associated with a 34 percent reduction in the rate of death. Median OS was 21.4 months for patients receiving CABOMETYX versus 16.5 months for those receiving everolimus (HR=0.66, 95% CI 0.53-0.83, P=0.0003).

Cabozantinib benefit in OS was robust and consistent across all pre-specified subgroups. In particular, benefit was observed regardless of risk category, location and extent of tumor metastases, and tumor MET expression level. These results were presented on June 5, 2016 at the ASCO Annual Meeting and concurrently published in *The Lancet Oncology*.[2]

At the time of the analysis, the median duration of treatment in the trial was 8.3 months with CABOMETYX versus 4.4 months with everolimus. Dose reductions occurred for 62 percent and 25 percent of patients, respectively. Discontinuation rate due to an adverse event not related to disease progression was 12 percent with CABOMETYX and 11 percent with everolimus.

**About Advanced Renal Cell Carcinoma**

The American Cancer Society's 2016 statistics cite kidney cancer as among the top ten most commonly diagnosed forms of cancer among both men and women in the U.S.[3] Clear cell RCC is the most common type of kidney cancer in adults.[4] 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 percent, with no identified cure for the disease.[3] Approximately 17,000 patients in the U.S. and 37,000 globally require second-line or later treatment.[5]

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.[6,7] These proteins promote tumor angiogenesis (blood vessel growth), growth, invasiveness and metastasis.[8-11] MET and AXL may provide escape pathways that drive resistance to VEGFR inhibitors.[7,8]

**About CABOMETYX**

CABOMETYX 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, the tablet formulation of cabozantinib, 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 January 28, 2016, the European Medicines Agency (EMA) validated Exelixis' Marketing Authorization Application (MAA) for cabozantinib as a treatment for patients with advanced renal cell carcinoma who have received one prior therapy. The MAA has been granted accelerated assessment, making it eligible for a 150-day review, versus the standard 210 days. On February 29, 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.

**Important Safety Information**

**Hemorrhage:** Severe hemorrhage occurred with CABOMETYX. The incidence of Grade ≥3 hemorrhagic events was 2.1% in CABOMETYX-treated patients and 1.6% in everolimus-treated patients. Fatal hemorrhages also occurred in the cabozantinib clinical program. Do not administer CABOMETYX to patients that have or are at risk for severe hemorrhage.

**Gastrointestinal (GI) Perforations and Fistulas:** Fistulas were reported in 1.2% (including 0.6% anal fistula) of CABOMETYX-treated patients and 0% of everolimus-treated patients. GI perforations were reported in 0.9% of CABOMETYX-treated patients and 0.6% of everolimus-treated patients. Fatal perforations occurred in the cabozantinib clinical program. Monitor patients for symptoms of fistulas and perforations. Discontinue CABOMETYX in patients who experience a fistula that cannot be appropriately managed or a GI perforation.

**Thrombotic Events:** CABOMETYX treatment results in an increased incidence of thrombotic events. Venous thromboembolism was reported in 7.3% of CABOMETYX-treated patients and 2.5% of everolimus-treated patients. Pulmonary embolism occurred in 3.9% of CABOMETYX-treated patients and 0.3% of everolimus-treated patients. Events of arterial thromboembolism were reported in 0.9% of CABOMETYX-treated patients and 0.3% of everolimus-treated patients. Fatal thrombotic events occurred in the cabozantinib clinical program. Discontinue CABOMETYX in patients who develop

an acute myocardial infarction or any other arterial thromboembolic complication.

**Hypertension and Hypertensive Crisis:** CABOMETYX treatment results in an increased incidence of treatment-emergent hypertension. Hypertension was reported in 37% (15% Grade ≥3) of CABOMETYX-treated patients and 7.1% (3.1% Grade ≥3) of everolimus-treated patients. Monitor blood pressure prior to initiation and regularly during CABOMETYX treatment. Withhold CABOMETYX for hypertension that is not adequately controlled with medical management; when controlled, resume CABOMETYX at a reduced dose. Discontinue CABOMETYX for severe hypertension that cannot be controlled with anti-hypertensive therapy. Discontinue CABOMETYX if there is evidence of hypertensive crisis or severe hypertension despite optimal medical management.

**Diarrhea:** Diarrhea occurred in 74% of patients treated with CABOMETYX and in 28% of patients treated with everolimus. Grade 3 diarrhea occurred in 11% of CABOMETYX-treated patients and in 2% of everolimus-treated patients. Withhold CABOMETYX in patients who develop intolerable Grade 2 diarrhea or Grade 3-4 diarrhea that cannot be managed with standard antidiarrheal treatments until improvement to Grade 1; resume CABOMETYX at a reduced dose. Dose modification due to diarrhea occurred in 26% of patients.

**Palmar-Plantar Erythrodysesthesia Syndrome (PPES):** Palmar-plantar erythrodysesthesia syndrome (PPES) occurred in 42% of patients treated with CABOMETYX and in 6% of patients treated with everolimus. Grade 3 PPES occurred in 8.2% of CABOMETYX-treated patients and in <1% of everolimus-treated patients. Withhold CABOMETYX in patients who develop intolerable Grade 2 PPES or Grade 3 PPES until improvement to Grade 1; resume CABOMETYX at a reduced dose. Dose modification due to PPES occurred in 16% of patients.

**Reversible Posterior Leukoencephalopathy Syndrome (RPLS):** RPLS, a syndrome of subcortical vasogenic edema diagnosed by characteristic finding on MRI, occurred in the cabozantinib clinical program. Perform an evaluation for RPLS in any patient presenting with seizures, headache, visual disturbances, confusion, or altered mental function. Discontinue CABOMETYX in patients who develop RPLS.

**Embryo-fetal Toxicity:** CABOMETYX 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 treatment with CABOMETYX and for 4 months after the last dose.

**Adverse Reactions:** The most commonly reported (≥25%) adverse reactions are: diarrhea, fatigue, nausea, decreased appetite, PPES, hypertension, vomiting, weight decreased, and constipation.

**Drug Interactions: Strong CYP3A4 inhibitors and inducers:** Reduce the dosage of CABOMETYX if concomitant use with strong CYP3A4 inhibitors cannot be avoided. Increase the dosage of CABOMETYX if concomitant use with strong CYP3A4 inducers cannot be avoided.

**Lactation:** Advise a lactating woman not to breastfeed during treatment with CABOMETYX and for 4 months after the final dose.

**Reproductive Potential: Contraception—**Advise females of reproductive potential to use effective contraception during treatment with CABOMETYX and for 4 months after the final dose. **Infertility —**CABOMETYX may impair fertility in females and males of reproductive potential.

**Hepatic Impairment:** Reduce the CABOMETYX dose in patients with mild (Child-Pugh score [C-P] A) or moderate (C-P B) hepatic impairment. CABOMETYX is not recommended for use in patients with severe hepatic impairment.

**Please see full Prescribing Information at https://cabometyx.com/downloads/cabometyxuspi.pdf.**

**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 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 or follow @ExelixisInc on Twitter.

**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.ipsen.com.

**Exelixis Forward-Looking Statement Disclaimer**

This press release contains forward-looking statements, including, without limitation, statements related to: the presentation of positive data from subgroup analyses of the pivotal METEOR trial at the 2016 ASCO Annual Meeting; Exelixis' dedication to exploring the full potential of CABOMETYX; the eligibility for an expedited review of Exelixis' MAA for cabozantinib in advanced RCC by the EMA; 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," "dedication," "potential," "eligible," "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 availability of data at the referenced times; Exelixis’ ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; risks and uncertainties related to regulatory review and approval processes and Exelixis’ compliance with applicable legal and regulatory requirements; 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’ dependence on its relationship with Ipsen, including, the level of Ipsen’s investment in the resources necessary to successfully commercialize cabozantinib in the territories where it is approved; Exelixis’ dependence on its relationship with Genentech/Roche with respect to cobimetinib and Exelixis’ ability to maintain its rights under the collaboration; 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’ annual report on Form 10-Q filed with the Securities and Exchange Commission ( SEC) on May 4, 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.

**Ipsen Forward-Looking Statement Disclaimer**

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 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 2014 Registration Document available on its website (www.ipsen.com).

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Source: Exelixis, Inc.

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