

Ipsen announces data presentations of cabozantinib (Cabometyx™), lanreotide (Somatuline® Autogel®) and telotristat ethyl* at the European Society for Medical Oncology (ESMO) 2016 congress

Paris, France, 27 September 2016 – Ipsen (Euronext: IPN; ADR: IPSEY), a global specialty-driven pharmaceutical group, today announced that Cabometyx™ (cabozantinib), Somatuline® Autogel® (lanreotide) and telotristat ethyl (*previously known as telotristat etiprate) will be the subject of 16 presentations at the European Society for Medical Oncology (ESMO) 2016 congress:

Cabozantinib to be featured in eight presentations

CABOSUN results accepted as late-breaker presentation in oral session at the Presidential Symposium

[LBA30] “CABOzantinib versus SUNitinib (CABOSUN) as initial targeted therapy for patients with metastatic renal cell carcinoma (mRCC) of poor and intermediate risk groups: Results from ALLIANCE A031203 Trial.”

Dr. Toni Choueiri, Director, Lank Center for Genitourinary Oncology, Dana-Farber Cancer Institute, Boston, Massachusetts, USA

Session: Presidential session 3

Oral presentation Monday, October 10, 4:30 – 6:10 p.m. CEST, Copenhagen

Note: This is a National Cancer Institute Cancer Therapy Evaluation Program (NCI-CTEP) study.

Poster Discussion

[774PD] “A phase I study of cabozantinib plus nivolumab (CaboNivo) in patients (pts) with refractory metastatic urothelial carcinoma (mUC) and other genitourinary (GU) tumors.”

Dr. Andrea Borghese Apolo, Genitourinary Malignancies Branch, Center for Cancer Research, National Cancer Institute, National Institutes of Health, Bethesda, Maryland, USA

Session: Genitourinary Tumours, Non-Prostate

Poster presented Sunday, October 9, 4:30 – 5:30 p.m. CEST, Athens

Note: This is an NCI-CTEP study.

Poster Presentations

[787P] “A phase II study of cabozantinib in patients (pts) with relapsed/refractory metastatic urothelial carcinoma (mUC).”

Dr. Rosa Nadal, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University, Baltimore, Maryland, USA

Session: Genitourinary Tumours, Non-Prostate



Poster presented Sunday, October 9, 1 – 2 p.m. CEST, Hall E

Note: This is an NCI-CTEP study.

[814P] “Efficacy of cabozantinib (cabo) vs everolimus (eve) by metastatic site and tumor burden in patients (pts) with advanced renal cell carcinoma (RCC) in the phase 3 METEOR trial.”

Dr. Thomas Powles, Barts Cancer Institute, Cancer Research UK Experimental Cancer Medicine Centre, Queen Mary University of London, Royal Free NHS Trust, London, GB

Session: Genitourinary Tumours, Non-Prostate

Poster presented Sunday, October 9, 1 – 2 p.m. CEST, Hall E

[815P] “Evaluation of the novel “trial within a trial” design of METEOR, a randomized phase 3 trial of cabozantinib versus everolimus in patients (pts) with advanced renal cell carcinoma (RCC).”

Colin Hessel, Exelixis, Inc., South San Francisco, California, USA

Session: Genitourinary Tumours, Non-Prostate

Poster presented Sunday, October 9, 1 – 2 p.m. CEST, Hall E

[816P] “Quality of life (QoL) in the phase 3 METEOR trial of cabozantinib vs everolimus for advanced renal cell carcinoma (RCC).”

Dr. David Cella, Department of Medical Social Sciences, Northwestern University Feinberg School of Medicine, Chicago, Illinois, USA

Session: Genitourinary Tumours, Non-Prostate

Poster presented Sunday, October 9, 1 – 2 p.m. CEST, Hall E

[818P] “Analysis of regional differences in the phase 3 METEOR study of cabozantinib (cabo) versus everolimus (eve) in advanced renal cell carcinoma (RCC).”

Dr. Nizar Tannir, University of Texas, MD Anderson Cancer Center, Houston, Texas, USA

Session: Genitourinary Tumours, Non-Prostate

Poster presented Sunday, October 9, 1 – 2 p.m. CEST, Hall E

[1421TiP] “A randomized double-blind phase II study evaluating the role of maintenance therapy with cabozantinib in high grade undifferentiated uterine sarcoma (HGUS) after stabilization or response to doxorubicin +/- ifosfamide following surgery or in metastatic first line treatment.”

Dr. Isabelle Ray-Coquard, Cancer Research Center of Lyon, Lyon, France

Session: Basic science

Poster presented Monday, October 10, 1 – 2 p.m. CEST, Hall E

Note: This is an investigator-sponsored trial.

Lanreotide (Somatuline® Autogel®) will be featured in 6 presentations:

[438P] “Efficacy of lanreotide autogel/depot (LAN) vs placebo (PBO) for symptomatic control of carcinoid syndrome (CS) in neuroendocrine tumor (NET) patients from the ELECT study”



Dr Edward Wolin, Montefiore Einstein Center for Cancer Care, Bronx, NY, USA

Session: Endocrine and neuroendocrine tumours

Poster presented Saturday, October 8, 1 – 2 p.m. CEST, Hall E

[440P] “Longer term efficacy of lanreotide autogel/depot (LAN) for symptomatic treatment of carcinoid syndrome (CS) in neuroendocrine tumor (NET) patients from the ELECT open label study”

Dr George Fisher. Stanford University School of Medicine, Stanford, CA, USA

Session: Endocrine and neuroendocrine tumours

Poster presented Saturday, October 8, 1-2 p.m. CEST, Hall E

[439P] “Long-term safety/tolerability of lanreotide autogel/depot (LAN) treatment for metastatic intestinal and pancreatic neuroendocrine tumours (NETs): final results of the CLARINET open-label extension (OLE)”

Dr Martyn Caplin, Royal Free Hospital, London, UK

Session: Endocrine and neuroendocrine tumours

Poster presented Saturday, October 8, 1 – 2 p.m. CEST, Hall E

[449TiP] “Safety and Efficacy of Lanreotide Autogel/Depot Every 14 Days for Patients with Pancreatic or Midgut Neuroendocrine Tumours Progressing on Lanreotide Every 28 Days: The Prospective, International CLARINET FORTE Study”

Dr Marianne Pavel. Charité University Medicine, Berlin, Germany

Session: Endocrine and neuroendocrine tumours

Poster presented Saturday, October 8, 1 – 2 p.m. CEST, Hall E

[450TiP] “Safety of lanreotide 120 mg ATG in combination with metformin in patients with advanced well-differentiated gastro-intestinal (GI) or lung carcinoids. A pilot, one-arm, open-label, prospective study: The MetNET-2 trial”

F. De Braud et al.

Session: Endocrine and neuroendocrine tumours

Poster presented Saturday, October 8, 1-2 p.m. CEST, Hall E

Note: This is a National Cancer Institute Milan sponsored study

[451TiP] “Combined Lanreotide Autogel and Temozolomide Therapy in Progressive Neuroendocrine Tumours: The SONNET Study”

Dr Dieter Hörsch, Zentralklinik Bad Berka, Bad Berka, Germany

Session: Endocrine and neuroendocrine tumours

Poster presented Saturday, October 8, 1 – 2 p.m. CEST, Hall E



Telotristat ethyl will be featured in one presentation:

[422PD] “Integrated placebo-controlled safety analysis from clinical studies of telotristat ethyl for the treatment of carcinoid syndrome”

Dr Matthew Kulke, Dana-Farber Cancer Institute, Boston, MA, USA

Session: Endocrine and neuroendocrine tumours

Poster discussion, Monday, October 10, 11-12 a.m. CEST, Room Berlin

In addition, Ipsen supported a collaborative study to understand the epidemiology of NET in European countries:

[424PD] “Prevalence of gastroenteropancreatic and lung neuroendocrine tumours in the European Union”

A. Bergamasco et al.

Session: Endocrine and neuroendocrine tumours

Poster discussion, Monday, October 10, 11-12 a.m. CEST, Room Berlin

Ipsen and Exelixis will host a joint investor / media event on October 10, 2016 at 6:30 p.m. (room 21, 1st floor, press area, Bella Center). Further information will follow with webcast and conference call details.

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.



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 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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