

Ipsen to initiate a proof-of-concept study with tasquinimod in additional cancer indications

Tasquinimod's unique mode of action potentially attractive in multiple malignant tumors

Paris (France), 19 October 2012 – Ipsen (Euronext: IPN; ADR: IPSEY) today announced that it will shortly initiate a new phase II, proof-of-concept clinical trial with tasquinimod in a so-called umbrella study evaluating the compound in four different tumor types. The study will evaluate the safety and efficacy of tasquinimod in advanced or metastatic hepato-cellular, ovarian, renal cell and gastric carcinomas in patients who have progressed after standard anti-tumor therapies.

Tasquinimod's unique mode of action is highly relevant to target multiple malignant diseases beyond prostate cancer. The compound's immunomodulatory and anti-angiogenic properties are believed to be pertinent in addressing unmet medical need in a broad wealth of carcinomas.

Claude Bertrand, Executive Vice-President R&D and Chief Scientific Officer of Ipsen said: *"With its unique mode of action we believe that tasquinimod should be assessed beyond prostate cancer. We hope that this innovative, proof-of-concept study in oncology will generate data on tasquinimod's biological and clinical activity and safety profile supporting further clinical development in high unmet medical need diseases."*

About the Proof of Concept "Umbrella" Phase II trial

The study is designed as a multi-center, open-label, early stopping design, proof of concept study. Tasquinimod clinical activity will be measured by the proportion of patients with progression free survival at pre-defined time-points.

About tasquinimod

In April 2011, Ipsen signed a broad co-development agreement with Active Biotech regarding tasquinimod. Active Biotech granted Ipsen the exclusive rights to commercialize tasquinimod worldwide, except for North and South America and Japan where Active Biotech retained all commercial and marketing rights. Under the terms of the agreement, both companies will co-develop tasquinimod for the treatment of cancer.

Tasquinimod has a distinct mode of action encompassing immunomodulatory, anti-angiogenic and anti-metastatic properties. Until today the development of tasquinimod was focused on the treatment of prostate cancer. Several clinical studies are currently ongoing:

- A phase III placebo-controlled study in men with bone-metastatic castration resistant prostate cancer (mCRPC) adequately powered to detect an overall survival improvement. The phase III study will

include about 1,200 patients in more than 250 centers. Recruitment is proceeding according to plan with top line results expected by the end of 2013.

- A Proof Of Concept “switch maintenance” Phase II clinical trial aiming at establishing the clinical efficacy of tasquinimod used as maintenance therapy in patients with metastatic castrate-resistant prostate cancer (mCRPC) who have not progressed after a first line docetaxel based chemotherapy. This is a randomized, double-blind placebo controlled, phase II trial investigating up to 1 mg/day of tasquinimod versus placebo in about 150 patients. The primary endpoint of the study is radiological progression free survival. The study will be recruited across about 50 centers in Europe.
- A Phase I investigator-sponsored clinical trial with the primary objective to determine the recommended dose of tasquinimod in combination with cabazitaxel based on safety and tolerability in heavily pretreated men with mCRPC. Secondary objectives include efficacy as measured by progression-free survival (PFS), and overall survival (OS). The study will include about 30 patients.

Additionally, a previous Phase II placebo-controlled study in men with asymptomatic/mildly symptomatic metastatic castration resistant prostate cancer, showed a higher fraction of patients with no disease progression during the six-month period of treatment using tasquinimod. These Phase II results were published in Journal of Clinical Oncology in September 2011. In June, 2012, overall survival (OS) data was presented at ASCO (American Society of Clinical Oncology).

About Ipsen

Ipsen is a global specialty-driven pharmaceutical company with total sales exceeding €1.1 billion in 2011. Ipsen’s ambition is to become a leader in specialty healthcare solutions for targeted debilitating diseases. Its development strategy is supported by four franchises: neurology / Dysport[®], endocrinology / Somatuline[®], uro-oncology / Decapeptyl[®] and hemophilia. 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. In 2011, R&D expenditure totaled more than €250 million, above 21% of Group sales. The Group has total worldwide staff of close to 4,500 employees. 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.

Ipsen’s 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.

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 Generics that might translate into loss of market shares.

Furthermore, the Research and Development process involves several stages each of which involve 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. 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 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.

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