

Ipsen presents preliminary results of exploratory proof-of-concept study with tasquinimod in four advanced tumor types at the ESMO 2014 Congress

- **Clinical data not supporting further development of tasquinimod in monotherapy in heavily pretreated patients with advanced ovarian, renal cell and gastric carcinomas**
- **Hepatocellular cohort continuing with results expected 2015**
- **Biomarker analyses ongoing to further characterize tasquinimod mode of action**

Paris (France), 27 September 2014 – Ipsen (Euronext: IPN; ADR: IPSEY) today announced the presentation at the ESMO 2014 Congress (26-30 September in Madrid) of the preliminary results of the phase II proof-of-concept clinical trial with tasquinimod in monotherapy, evaluating the compound in four advanced tumor types.

The main objective of the study was to determine the clinical activity of tasquinimod in advanced hepatocellular (HCC), ovarian (OC), renal cell (RCC) and gastric (GC) carcinomas in patients who had progressed after standard anti-tumor therapies. Primary endpoint was the PFS rate at a predefined time for each cohort. Secondary objectives included PFS, response rate, OS, safety, pharmacokinetics and biomarkers.

The data did not support further development of tasquinimod in monotherapy in heavily pretreated patients with advanced OC, RCC and GC. Pharmacokinetic and biomarkers analyses are ongoing. Preliminary results from the futility analysis reported sufficient clinical activity to complete the recruitment of the HCC cohort for which results are expected in 2015.

The safety profile was consistent with the known safety profile of tasquinimod in previous studies.

Data from the HCC cohort was presented (Poster p-171)¹ at the International Liver Cancer Association 8th Annual Conference (5–7 September 2014, Kyoto, Japan).

¹ Exploring the activity of tasquinimod, a compound with a novel mechanism of action, in patients with advanced hepatocellular carcinoma (HCC), previously treated with sorafenib

About the study

The “Umbrella” trial is a Phase II, multicenter, open-label, proof of concept study of tasquinimod in patients with advanced hepatocellular (HCC), ovarian (OC), renal cell (RCC) and gastric (GC) carcinomas

About tasquinimod

Tasquinimod is a novel small molecule that targets the tumor microenvironment by binding to S100A9 and modulating regulatory myeloid cell functions, exerting immunomodulatory, anti-angiogenic and anti-metastatic properties. Tasquinimod may also suppress the tumor hypoxic response, contributing to its effect on the tumor microenvironment. Today the development of tasquinimod is principally focused on the treatment of prostate cancer, but early clinical studies in other cancer indications are performed.

About Ipsen

Ipsen is a global specialty-driven pharmaceutical company with total sales exceeding €1.2 billion in 2013. Ipsen’s ambition is to become a leader in specialty healthcare solutions for targeted debilitating diseases. Its development strategy is supported by 3 franchises: neurology, endocrinology and uro-oncology. 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 2013, R&D expenditure totaled close to €196 million, representing more than 16% of Group sales. Moreover, Ipsen also has a significant presence in primary care. The Group has close to 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 Statements

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,

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