

Ipsen initiates a phase II “Switch maintenance” trial in metastatic castrate-resistant prostate cancer with tasquinimod

Paris (France) and Lund (Sweden), 3 October 2012 – Ipsen (Euronext: IPN; ADR: IPSEY) and Active Biotech (NASDAQ OMX NORDIC: ACTI) today announced the initiation of a new phase II proof of concept clinical trial, evaluating the activity of tasquinimod in advanced metastatic castrate resistant prostate cancer patients. The study aims 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.

Karim Fizazi, Head of the Cancer Medicine Department of the Institut Gustave Roussy (IGR) in France and Principal investigator of the study said: *“In current clinical practice, metastatic castrate resistant prostate cancer patients with non-progressive disease after docetaxel treatment are not proposed any medication as no reference/standard treatment exists. These patients remain untreated until disease progression. Prolongation of the response to first line chemotherapy (consolidation) represents an unmet need for which patients and physicians request further therapeutic options. ‘Switch maintenance’ therapy with manageable safety profile such as tasquinimod could be one strategy to prolong treatment response, without significantly compromising quality of life.”*

Claude Bertrand, Executive Vice-President R&D, Chief Scientific Officer of Ipsen said: *“Ipsen is highly committed to the treatment of prostate cancer. Maintenance therapy in prostate cancer might be a viable therapeutic paradigm, as demonstrated in other tumor types.”* **Claude Bertrand** added: *“With its distinct mode of action and the encouraging data demonstrated in phase II, tasquinimod has the potential to provide advanced prostate cancer patients with a new treatment option supported by an innovative therapeutic strategy.”*

The “switch maintenance” trial is part of the initial agreement with Active Biotech to enhance tasquinimod’s data package beyond the ongoing phase III placebo-controlled study in men with bone-metastatic CRPC, which has been adequately powered to detect an OS 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.

About the Proof Of Concept “switch maintenance” Phase II trial

A global, 2:1 randomized, placebo controlled, double-blind Phase II trial investigating up to 1 mg/day of tasquinimod versus placebo in 150 metastatic castrate resistant prostate cancer (mCRPC) patients who have not progressed after a first line docetaxel based chemotherapy. The primary endpoint of the study is radiological progression free survival. The study will be recruited across about 50 centers in Europe.

About tasquinimod

Tasquinimod has a pleiotropic mode of action which includes immunomodulatory, anti-angiogenic and anti-metastatic activity. Today the development of tasquinimod is principally focused on the treatment of prostate cancer. It was announced in December 2009 that the primary endpoint of the Phase II clinical study, to show a higher fraction of patients with no disease progression during the six-month period of treatment using tasquinimod, had been met. 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).

Active Biotech AB (NASDAQ OMX NORDIC: ACTI) is a biotechnology company with focus on autoimmune/inflammatory diseases and cancer. Projects in or entering pivotal phase are laquinimod, an orally administered small molecule with unique immunomodulatory properties for the treatment of multiple sclerosis, tasquinimod for prostate cancer as well as ANYARA for use in cancer targeted therapy, primarily of renal cell cancer. In addition, laquinimod is in Phase II development for Crohn's and Lupus. An additional project in clinical development is the orally administered compound 57-57 for Systemic Sclerosis. Please visit <http://www.activebiotech.com> for more information.

Active Biotech's Safe Harbor Statement in Accordance with the Swedish Securities Market Act

This press release contains certain forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors that could cause the actual results, performance or achievements of the company, or industry results, to differ materially from any future results, performance or achievement implied by the forward-looking statements. The company does not undertake any obligation to update or publicly release any revisions to forward-looking statements to reflect events, circumstances or changes in expectations after the date of this press release.

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.ipse.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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