

Active Biotech's and Ipsen's Tasquinimod shows encouraging overall survival improvement in castrate resistant prostate cancer

Phase II Overall Survival data presented at the 2012 ASCO Annual Meeting

Lund (Sweden) and Paris (France), June 4, 2012. Active Biotech (NASDAQ OMX NORDIC: ACTI) and Ipsen (Euronext: IPN; ADR: IPSEY) today presented overall survival (OS) data from the tasquinimod Phase II study in chemotherapy-naïve metastatic castrate resistant prostate cancer (CRPC) at the scientific conference "2012 ASCO Annual Meeting" held in Chicago (USA).

Today at 08:00 am CDT (3:00 pm CET) Dr. Andrew J. Armstrong from the Duke Cancer Institute (Durham, NC) presented "**Tasquinimod and survival in men with metastatic castration-resistant prostate cancer: Results of long-term follow-up of a randomized phase II placebo-controlled trial***" in a poster discussion session.

The intention-to-treat analysis showed median overall survival times (OS) of 33.4 vs. 30.4 months ($p=0.49$, HR 0.87, 95% CI 0.59-1.29, ITT) in favor of tasquinimod, longer than previously reported in this metastatic prostate cancer population. A stronger trend for survival benefit is observed in patients with bone metastases; median OS was 34.2 vs. 27.1 months ($p=0.19$, HR 0.73, 95% CI 0.46-1.17). This phase II clinical trial was designed to test the safety and efficacy of tasquinimod. Noteworthy, 41 (61%) patients crossed-over from placebo to tasquinimod (mean time to cross-over approx. 5 months). Also, there were imbalances in baseline prognostic factor in favor of the placebo arm. These were addressed with a multivariate analysis of known CRPC prognostic factors. It demonstrated a statistically significant OS advantage for tasquinimod treated patients with a hazard ratio (HR) of 0.64 (95% CI 0.42-0.97, $p=0.034$), a decrease of approximately 40% in the instantaneous risk of event (death), accompanied by improvement in progression-free survival (HR 0.52, 95% CI 0.35-0.78, $p=0.001$).

*"Men with metastatic CRPC in this trial were unexpectedly found to have prolonged survival times beyond that previously reported in this patient population, despite a high fraction of patients with liver and lung metastases." says principal author **Andrew Armstrong**, MD ScM, Assistant Professor of Medicine and Surgery at Duke University and the Duke Prostate Center. "We also found that despite initial imbalances in baseline characteristics, the improvements in progression-free survival with tasquinimod may translate into improvements in overall survival, and, if confirmed in the ongoing phase 3 trial, suggests that tasquinimod may have an important role in the future treatment of men with CRPC."*

Tomas Leanderson, President and CEO of Active Biotech, said: *"These data further increase our strong confidence in tasquinimod as a valuable asset to address the huge medical need for hundreds of thousands of men with limited treatment options today".*

Claude Bertrand, Executive Vice-President R&D, Chief Scientific Officer of Ipsen said: *“We are thrilled with Tasquinimod’s phase II results as they underline the activity of the compound. With its differentiated mechanism of action, we look forward to completing the ongoing phase III and replicating these interesting results to propose an alternative treatment that does not target the androgen receptor pathway to progressing patients.”*

For more detailed information, please see www.asco.org. The presentation is available on Active Biotech’s web site www.activebiotech.com.

* A.J. Armstrong, M. Häggman, W.M. Stadler, J.R. Gingrich, V.J. Assikis, J. Polikoff, S.R. Denmeade, D.J. George, C. Andreou, W.R. Clark, P. Sieber, R. Agajanian, L. Belkoff, J-E. Damber, Ö. Nordle, G. Forsberg, M. A. Carducci, R. Pili.

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.

About Phase II

A global, pivotal, clinical trial 2:1 randomized, placebo controlled, double-blind Phase II trial investigating up to 1 mg/day of TASQ versus placebo in 206 asymptomatic patients with metastatic castrate resistant prostate cancer (CRPC). The primary endpoint, patients with disease progression at six months, was reached. The results showed that 6 month progression-free proportions for TASQ and placebo groups were 69% and 37%, respectively ($p < .0001$). The median progression free survival was 7.6 months for the TASQ group, compared to 3.3 months for the placebo group ($p = 0.0042$). TASQ treatment also had an effect on biomarkers relevant for prostate cancer progression and was generally well tolerated. Analysis of up to three years safety data from the Phase II study, presented at the EAU February 2012, show that treatment side effects were mild to moderate (~ 5% of AEs grade 3-4), manageable and less frequent after two months of therapy. The adverse events observed included gastrointestinal disorders, primarily observed initially during treatment, fatigue and musculoskeletal pain.

About Phase III

A global, pivotal, randomized, double-blind, placebo-controlled Phase III study of tasquinimod in patients with metastatic CRPC is ongoing. The aim of the study is to confirm tasquinimod’s efficacy on the disease, with radiological Progression Free Survival (PFS) as the primary endpoint and overall survival as secondary endpoint. The study will include about 1,200 patients in more than 250 clinics. Recruitment is proceeding according to plan with approximately 600 patients recruited so far. Top line results expected by the end of 2013.

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. Further projects in clinical development comprise the two orally administered compounds, 57-57 for Systemic Sclerosis and RhuDex[®] for rheumatoid arthritis. 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. R&D is focused on innovative and differentiated technological patient-driven 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.

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.

For further information:

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