





Active Biotech and Ipsen update the analysis plan for the 10TASQ10 trial evaluating tasquinimod in the treatment of prostate cancer

Primary PFS analysis now expected at the same time as first interim overall survival analysis in 2014

Lund (Sweden) and Paris (France), 25 April, 2013 - Active Biotech (NASDAQ OMX NORDIC: ACTI) and Ipsen (Euronext: IPN; ADR: IPSEY) today announced that the companies have updated the analysis plan for the 10TASQ10 trial, a global Phase III clinical trial evaluating tasquinimod in patients with metastatic castrate-resistant prostate cancer (mCRPC) who have not yet received chemotherapy.

The companies now plan to conduct the primary PFS analysis for the 10TASQ10 trial in 2014, at the same time as the first interim overall survival (OS) analysis. The time point for the OS interim analysis will be driven by the number of OS events. The specified number of radiographic progression-free survival (PFS) events for the primary end-point will have been exceeded at the time of interim OS analysis.

Dr. Claude Bertrand, Executive Vice president R&D, Chief Scientific Officer at Ipsen, stated: "Based on the new regulatory and medical environment in the field of prostate cancer, we have reviewed the analysis strategy for the 10TASQ10 trial. We now plan to conduct the 10TASQ10 primary PFS analysis in 2014 when more mature data on OS will be available."

"The strategy to use interim OS analysis is a very logical way to secure both PFS and OS data", said Michael Carducci, Professor of Oncology and Urology at the Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University and Principal Investigator for the 10 TASQ10 clinical trial.

Professor Tomas Leanderson, President & CEO Active Biotech stated: "To harness both PFS and OS data while the study is still blinded secures that this analysis plan provides us with the most robust data set in order to progress the development of the TASQ project."

The randomized, double-blind, placebo-controlled, Phase III 10TASQ10 trial met its enrollment target in December 2012 with 1,245 randomized patients as planned in the clinical protocol. The aim of the study is to confirm tasquinimod's efficacy, with radiological Progression Free Survival (PFS) as primary endpoint and overall survival (OS) as key secondary endpoint. The study recruited patients in 37 countries covering more than 200 centers.





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. Tasqunimod 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.

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. 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 tasquinimod group, compared to 3.3 months for the placebo group (p=0.0042).

Analysis of up to three years safety data from the Phase II study, presented at the EAU February 2012, showed 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.

In June, 2012, overall survival (OS) data was presented at ASCO (American Society of Clinical Oncology).

In October, 2012, biomarker data were presented at the scientific congress ESMO (European Society for Medical Oncology). The results support an effect of tasquinimod on both immunomodulation and angiogenesis positioning tasquinimod as a potentially unique therapeutic approach with a mechanism of action that does not target the androgen receptor pathway.

Also, in April 2013, the independent Data and Safety Monitoring Board (DSMB) monitoring the ongoing Phase III trial recommended that the study continues in accordance with the protocol since no safety-related issues were noted.

A new Phase II, proof-of-concept clinical trial was initiated and which aims at establishing the clinical efficacy of tasquinimod used as maintenance therapy in patients with mCRPC who have not progressed after a first-line docetaxel based chemotherapy.

Ipsen has also initiated an innovative Phase II proof-of-concept clinical trial with tasquinimod, to 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 therapies.

About Active Biotech

Active Biotech AB (NASDAQ OMX NORDIC: ACTI) is a biotechnology company with focus on autoimmune/inflammatory diseases and cancer. Projects in pivotal phase are laquinimod, an orally administered small molecule with unique immunomodulatory properties for the treatment of multiple sclerosis, TASQ for prostate cancer and ANYARA primarily for the treatment of renal cell cancer. In addition, laquinimod is in Phase II development for Crohn's and Lupus. The company also has one additional project in clinical development, the orally administered compound 57-57 for Systemic Sclerosis. Please visit 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





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About Ipsen

Ipsen is a global specialty-driven pharmaceutical company with total sales exceeding €1.2 billion in 2012. 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 2012, R&D expenditure totalled close to €250 million, representing more than 20% of Group sales. The Group has close to 4,900 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. 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 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. 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





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