



Press release

# Active Biotech and Ipsen report Tasquinimod (TASQ) phase II long term safety data at the 27<sup>th</sup> European Association of Urology (EAU) Congress

**Lund (Sweden)** and **Paris (France)**, **February 24**, **2012** – Active Biotech's (NASDAQ OMX NORDIC: ACTI) and Ipsen's (Euronext: IPN; ADR: IPSEY) castrate resistant prostate cancer project, TASQ, will be presented at the 27th Annual EAU Congress held in Paris on 24-28 February 2012. The presentation will detail the analysis of up to three years safety data from the TASQ Phase II study in chemotherapy-naïve metastatic castrate resistant prostate cancer (CRPC).

The poster "Long term safety and efficacy in a randomized multicenter international phase II study of tasquinimod in chemotherapy-naïve patients with metastatic castrate resistant prostate cancer" A.J. Armstrong, J.R. Gingrich, M. Häggman, W.M. Stadler, J.E. Damber, L. Belkoff, R. Clark, S. Brosman, O. Nordle, G. Forsberg, M.A. Carducci, R. Pili. will be presented on February 25 at 2:15 pm CET. The poster will combine the long term safety data and the already published encouraging efficacy data, published in the Journal of Clinical Oncology (JCO) in September 2011. The poster will be publically available after the presentation on <a href="https://www.activebiotech.com">www.activebiotech.com</a>.

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.

Andrew J. Armstrong, Associate Professor of Medicine and Surgery and Medical Oncologist at Duke University, tasquinimod Phase II investigator, said: "These long term safety data are of critical importance as tasquinimod is being evaluated in elderly men with castrate resistant prostate cancer, and standard treatment of these patients will include a sequence of active therapies used for long periods of time. These new data show that tasquinimod long term safety is acceptable. Tasquinimod may therefore be a suitable therapy to evaluate at an early stage in management of CRPC, either as monotherapy or in combination with other effective agents for prostate cancer, as it does not jeopardize the patient's chances to receive additional treatment".

A global, pivotal, randomized, double-blind, placebo-controlled Phase III study of TASQ in patients with metastatic CRPC is ongoing. The aim of the study is to confirm TASQ's effect on the disease, with radiological PFS as the primary endpoint and overall survival as secondary endpoint. The study will include about 1,200 patients in more than 250 clinics.

The independent Data and Safety Monitoring Board (DSMB) overseeing the ongoing Phase III clinical trial has recommended the study to proceed as per protocol as no safety concerns were identified.





# **About TASQ**

The development of TASQ is principally focused on the treatment of prostate cancer. Studies have concluded that TASQ exhibits immunomodulatory, anti-angiogenic and anti-metastatic activity. 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 TASQ, had been met. Final Phase II results were published in Journal of Clinical Oncology in September 2011. It was concluded that TASQ significantly slowed disease progression and improved Progression Free Survival (PFS) in patients with metastatic castrate-resistant prostate cancer (CRPC), alongside an acceptable side effect profile. Six month progression free proportion of patients for TASQ and placebo treatment groups were 69% and 37%, respectively (p<0.0001), with a median PFS of 7.6 vs. 3.3 months (p=0.0042).

# **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 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 as well as RhuDex<sup>TM</sup> for RA. Please visit www.activebiotech.com for more information.

Active Biotech is required under the Securities Markets Act to make the information in this press release public.

The information was submitted for publication at 08:30 a.m. CET on February 24, 2012.

### **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 2010, R&D expenditure totaled more than €220 million, above 20% 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.ipsen.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 loose 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 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 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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