

## Active Biotech and Ipsen announce completion of recruitment of tasquinimod clinical phase III study in prostate cancer

- **Full recruitment triggers a €10 million milestone payment to Active Biotech**

**Lund (Sweden) and Paris (France), December 10, 2012,** Active Biotech (NASDAQ OMX NORDIC: ACTI) and Ipsen (Euronext: IPN; ADR: IPSEY) today announced that the Phase III clinical trial for tasquinimod, a novel compound for the treatment of prostate cancer, is successfully enrolled with over 1,200 randomized patients as planned in the clinical protocol. This achievement triggers a €10 million milestone payment from Ipsen to Active Biotech.

This study is a global, pivotal, randomized, double-blind, placebo-controlled Phase III clinical trial of tasquinimod in patients with metastatic castrate resistant prostate cancer (mCRPC). 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 secondary endpoint. The study recruited patients in more than 250 centers all over the world.

**Marc de Garidel, Chairman and Chief Executive Officer of Ipsen,** said: *"The on-schedule recruitment of tasquinimod phase III clinical trial highlights Active Biotech's commitment and the growing interest from the medical community for an innovative and differentiated mode of action."* **Marc de Garidel** added: *"We now look forward to confirming the encouraging phase II results and bringing a new treatment option to patients with mCRPC."*

*"I am very satisfied by the speed of recruitment of prostate cancer patients into this study. We now look forward to the continued development of this global trial and the subsequent development of this unique drug also in other indications",* said **Tomas Leanderson, President & CEO Active Biotech.**

### **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. 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, 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.

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 October 2012, 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](http://www.activebiotech.com) for more information.

### **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<sup>®</sup>, endocrinology / Somatuline<sup>®</sup>, uro-oncology / Decapeptyl<sup>®</sup> 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.ipsen.com](http://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 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 cannot be certain that its partners will fulfill 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 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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