

## 600 Patients Recruited in Active Biotech's and Ipsen's tasquinimod Clinical Phase III Study

- **Half of target patient population recruited, triggering a €10 million milestone payment**

**Lund (Sweden) and Paris (France), May 21, 2012,** Active Biotech (NASDAQ OMX NORDIC: ACTI) and Ipsen (Euronext: IPN; ADR: IPSEY) today announced that recruitment to the global, pivotal, randomized, double-blind, placebo-controlled phase III study of tasquinimod in patients with metastatic castrate-resistant prostate cancer (CRPC) has reached an inclusion of 600 patients, half of the planned accrual. This triggers a €10 million milestone payment from Ipsen to Active Biotech.

The aim of the Phase III study is to confirm tasquinimod's efficacy on metastatic CRPC in the prechemotherapy setting, with radiological progression free survival (PFS) as the primary endpoint and overall survival (OS) as secondary endpoint. The 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.

**Marc de Garidel, Chairman and Chief Executive Officer of Ipsen,** said: *"The on-schedule recruitment of the 600th patient in the tasquinimod phase III clinical trial is a testimony of the interest of the medical community in the drug's novel and differentiated mode of action. In a crowded prostate cancer space, we also recognize the quality and diligence of the work of our partner Active Biotech to bring new therapies to patients."* **Marc de Garidel** added: *"Ipsen is now in the final stage of designing the randomized supportive study to be initiated before year-end and is getting ready to investigate tasquinimod in additional indications."*

**Tomas Leanderson, President and CEO of Active Biotech,** said: *"The successful recruitment into the ongoing phase III study indicates the level of interest for tasquinimod as an alternative treatment for CRPC. The partnership with Ipsen has significantly increased the potential of this novel approach to treat cancer."*

### **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. It was concluded that tasquinimod significantly slowed disease progression and improved Progression Free Survival (PFS) in chemo-naïve 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 ( $p = 0.0042$ ). 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. Preliminary overall survival data was released on May 18, 2012 which showed that median time to death was

34.2 vs. 30.2 months (tasquinimod vs placebo). A preliminary subgroup analysis using the PCWG2 (Prostate Cancer Clinical Trials Working Group 2) defined criteria showed that median time to death in the bone-metastatic subgroup was 34.2 vs. 25.6 months (tasquinimod vs placebo).

**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, TASQ 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<sup>®</sup> 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<sup>®</sup>, endocrinology / Somatuline<sup>®</sup>, uro-oncology / Decapeptyl<sup>®</sup> 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](http://www.ipсен.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 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

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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