

## **Active Biotech and Ipsen announce their decision to discontinue the development of tasquinimod in prostate cancer**

**Lund (Sweden) and Paris (France), 16 April 2015** – Active Biotech (NASDAQ STOCKHOLM: ACTI) and Ipsen (Euronext: IPN; ADR: IPSEY) today announced top line results of the 10TASQ10 study. While the study showed that tasquinimod reduced the risk of radiographic cancer progression or death compared to placebo (rPFS, HR=0.69, CI 95%: 0.60 – 0.80) in patients with metastatic castration resistant prostate cancer (mCRPC) who have not received chemotherapy, tasquinimod did not extend overall survival (OS, HR=1.09, CI 95%: 0.94 – 1.28).

Efficacy results together with preliminary safety data do not support positive benefit risk balance in this population. Therefore the companies have decided to discontinue all studies in prostate cancer. Full results will be presented at an upcoming scientific conference.

**Marc de Garidel, Chairman and Chief Executive Officer of Ipsen** stated: *"We are disappointed for prostate cancer patients. Ipsen remains strongly committed to oncology. We are grateful to the clinicians, caregivers, patients and their families who were involved in this study."*

**Professor Tomas Leanderson, President and Chief Executive Officer of Active Biotech** stated: *"The outcome of the 10TASQ10 study is a major disappointment based on the promising phase II results. However, the data at hand is unambiguous and cannot motivate further development of tasquinimod in this patient population. I want to thank the clinicians, caregivers, patients and their families who were involved in this study."*

Ipsen and Active Biotech are in communication with trial investigators, ethics committees and the relevant regulatory authorities, to provide them with updated and current information in compliance with local regulations. The companies are working with trial investigators and local regulatory authorities to ensure that patients who participated in the tasquinimod trials are transitioned to appropriate therapies so that trial participants receive appropriate care.

### **About tasquinimod**

Tasquinimod is a novel oral immunotherapy that targets the tumor microenvironment by binding to S100A9 and modulating regulatory myeloid cell functions, exerting immunomodulatory, anti-angiogenic and anti-metastatic properties. Today the development of tasquinimod principally has been focused on the treatment of prostate cancer, but early clinical studies in other cancer indications are performed.

### **About the 10TASQ10 trial**

The 10TASQ10 trial is a randomized, double-blind, placebo-controlled, global Phase III clinical trial evaluating tasquinimod in patients with metastatic castration resistant prostate cancer (mCRPC) who have not yet received chemotherapy. The aim of the 10TASQ10 study is to confirm tasquinimod's efficacy, with radiological Progression Free Survival (rPFS) as primary endpoint and overall survival (OS) as key secondary endpoint. The Phase III 10TASQ10 trial met its enrollment target in December 2012 with more than 1,200 randomized patients as planned in the clinical protocol.

### **About Active Biotech**

Active Biotech AB (publ) (Nasdaq Stockholm: ACTI) is a biotechnology company with focus on neurodegenerative diseases and cancer. Projects in pivotal phase are laquinimod, an orally administered small molecule with unique immunomodulatory properties for the treatment of multiple sclerosis, and tasquinimod, an oral immunomodulatory, anti-metastatic substance for the treatment of prostate cancer. The objective of the preclinical ISI project is to produce new, patentable chemical compounds for treatment of diseases in the company's focus areas. Please visit [www.activebiotech.com](http://www.activebiotech.com) for more information.

### **About Ipsen**

Ipsen is a global specialty-driven biotechnological group with total sales exceeding €1.2 billion in 2014. Ipsen sells more than 20 drugs in more than 115 countries, with a direct commercial presence in 30 countries. 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 urology-oncology. Ipsen's commitment to oncology is exemplified through its growing portfolio of key therapies improving the care of patients suffering from prostate cancer, bladder cancer or neuro-endocrine tumors. Ipsen also has a significant presence in primary care. 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, located in the heart of the leading biotechnological and life sciences hubs (Les Ulis, France; Slough/Oxford, UK; Cambridge, US). In 2014, R&D expenditure totaled close to €187 million, representing about 15% of Group sales. The Group has more than 4,500 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.ipсен.com](http://www.ipсен.com).

### **Ipsen Forward Looking Statements**

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. Use of the words "believes," "anticipates" and "expects" and similar expressions are intended to identify forward-looking statements, including the Group's expectations regarding future events, including regulatory filings and determinations. 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 generic products 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. There can be no guarantees a product will receive the necessary regulatory approvals or that the product will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Other risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the Group's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the Group's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions. 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 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.

**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.

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*Active Biotech is obligated to publish the information contained in this press release in accordance with the Swedish Securities Market Act. This information was provided to the media for publication 7:00 am. CET on 16 April 2015.*