



# Active Biotech and Ipsen enter into a broad partnership for the co-development and commercialization of TASQ in uro-oncology

- Ipsen's Uro-Oncology pipeline strengthened, with a phase III product for the treatment of castrate-resistant prostate cancer
- A potential companion drug for Ipsen's Decapeptyl<sup>®</sup>
- A drug with a unique mechanism of action targeting angiogenesis and immunomodulation

Lund (Sweden) and Paris (France), 18 April 2011 – Active Biotech AB (NASDAQ OMX NORDIC: ACTI) and Ipsen (Euronext: IPN; ADR: IPSEY) announced today that they have entered into a broad partnership to co-develop and commercialize Active Biotech's investigational compound Tasquinimod "TASQ". A global Phase III trial of TASQ in men with metastatic castrate-resistant prostate cancer (CRPC) was recently initiated by Active Biotech and patient recruitment is ongoing.

**Marc de Garidel, Chairman and Chief Executive Officer of Ipsen** stated: "This new partnership will broaden the scope of our uro-oncology franchise. Subject to the success of the ongoing phase III clinical trial for the treatment of metastatic castrate-resistant prostate cancer and following market approval, TASQ will perfectly fit in our current portfolio, alongside the sustained-release formulations of Decapeptyl<sup>®</sup>. We continue to fulfill Ipsen's commitment to offer physicians and patients a comprehensive range of complementary medical solutions for the treatment of prostate cancer. We are excited to work with Active Biotech as this partnership leverages our longstanding and recognized expertise in this severely debilitating disease."

"We are excited to initiate the development of TASQ with Ipsen, who has a proven track record and strong R&D capabilities within prostate cancer. We consider Ipsen an ideal partner for Active Biotech and with this partnership a powerful development and commercialization strategy for TASQ has been secured. "said **Tomas Leanderson, President & CEO of Active Biotech**.

### About the agreement

Under the terms of the agreement, Active Biotech granted Ipsen exclusive rights to commercialize TASQ worldwide, except for North and South America and Japan where Active Biotech retains all commercial and marketing rights. Both companies will co-develop TASQ for the treatment of castrate-resistant prostate cancer, with the possibility to develop TASQ in other cancer indications.

Active Biotech is responsible for conducting and funding the Phase III pivotal clinical trial and will receive up to €200 million consisting of an upfront payment of €25 million and additional payments contingent upon achievement of clinical, regulatory and commercial milestones. In addition, Ipsen will pay Active Biotech progressive double-digit royalties on its net sales and will conduct and fund a European supportive study in prostate cancer patients out of its R&D budget. Eventual costs to develop TASQ in future other cancer indications will be shared.





## About TASQ

TASQ (tasquinimod, ABR-215050) binds to a molecule called S100A9 which is expressed in the white blood cells involved in the regulation of immune responses. S100A9 interacts with two known pro-inflammatory receptors (Toll like receptor 4 (TLR4) and receptor of advanced glycation end products (RAGE)) and this interaction is inhibited by TASQ (Björk et al PLoS Biology, April 2009).

The development of TASQ is currently focused on the treatment of prostate cancer. TASQ is an antiangiogenic compound, meaning that it cuts off the supply of nutrients to the tumor. Upregulation of thrombospondin-1 (TSP1) has been identified as one important component in order to understand and explain the anti-angiogenic mechanism of TASQ treatment of prostate cancer (Olsson et al, Mol Cancer May 2010).

The previously concluded clinical trial was a 2:1 randomized, placebo controlled, double-blind Phase II trial investigating up to 1 mg/day of TASQ versus placebo in 206 asymptomatic patients with metastatic castrate resistant prostate cancer (CRPC). The primary endpoint, patients with disease progression at six months, was reached. The results showed that the fraction of patients with disease progression during the six-month period was 31% for patients treated with TASQ compared with 66% for placebo-treated patients. The median progression-free survival was 7.6 months for the TASQ group, compared to 3.3 months for the placebo group (p=0.0042). TASQ treatment also had an effect on biomarkers relevant for prostate cancer progression and was generally well tolerated.

The ongoing clinical trial (funded by Active Biotech) is a global, randomized, double-blind, placebo-controlled Phase III trial in patients with metastatic CRPC. The aim of the study is to confirm TASQ's effect on the disease, with radiological progression-free survival (PFS) as the primary endpoint and overall survival as the secondary endpoint. The study will include about 1,200 patients in more than 250 clinics (www.clinicaltrials.gov)

### About Prostate Cancer

Prostate cancer is the most common cancer form among men. Its occurrence is strongly age-related and it is very rare before the age of 50. Prostate cancer has highly varying degrees of severity. Despite a relatively good prognosis, prostate cancer is the second most common cause of cancer death among men.

Every year about 220,000 new cases are diagnosed in the US alone (American Cancer Society 2010) and 226 000 new cases for European G5 (source : Datamonitor 2010). The global market for drugs used in the treatment of prostate cancer was estimated at USD 5.4 billion for 2009 (GlobalData 2010).

### About lpsen's pipeline in uro-oncology

Ipsen's pipeline in uro-oncology contains Decapeptyl<sup>®</sup>. The active substance in Decapeptyl<sup>®</sup> is triptorelin, a decapeptide analogue of GnRH (Gonadotrophin Releasing Hormone), a hormone secreted by the hypothalamus, which initially stimulates the release of pituitary gonadotrophins (hormones produced by the pituitary gland), which in turn control hormonal secretions by the testes and ovaries. Decapeptyl<sup>®</sup> contains a formulation that was initially developed and continues to be used mainly in the treatment of advanced metastatic prostate cancer. Additional indications have been subsequently developed.

Decapeptyl<sup>®</sup> is available in monthly or quarterly sustained-release formulations, as well as a daily formulation. In addition, Ipsen and its partner Debiopharm submitted a marketing authorization application for 6-month triptorelin 22.5 mg in Europe in September 2008. Ipsen and Debiopharm announced the





completion of the European decentralized registration procedure for the 6-month sustained-release formulation of Decapeptyl<sup>®</sup>. This formulation is therefore available in some countries of the European market since 2010.

Decapeptyl<sup>®</sup> was initially launched in France in 1986. At 31 December 2010, Decapeptyl<sup>®</sup> had marketing authorizations in over 60 countries, including 21 in Europe.

### About Ipsen

Ipsen is a global biopharmaceutical group, with sales exceeding €1.1 billion in 2010. The Group has total worldwide staff of more than 4,400 employees, of which more than 900 contribute to the discovery and development of innovative drugs for patient care. Ipsen's development strategy is based on fast growing specialty care drugs in oncology, endocrinology, neurology and hematology and on primary care drugs. This strategy is supported by an active policy of partnerships. Ipsen's research & development (R&D) centers and its peptide & protein engineering platform give the Group a strong competitive edge. In 2010, R&D expenditure totaled more than €220 million, above 20% of Group sales. 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 overthe-counter market in the United States under the symbol IPSEY. For more information on Ipsen, visit www.ipsen.com.

### About Active Biotech

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 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 SLE and Systemic Sclerosis as well as RhuDex<sup>TM</sup> for RA. Please visit <u>www.activebiotech.com</u> for more information.

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### **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. 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. Notably, future currency fluctuations may negatively impact the profitability of the Group and its ability to reach its objectives. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties. The Group does not commit nor gives any guarantee that it will meet the targets mentioned above. 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.

### 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.

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 on 18 April 2011, at 7:30 am CET.