

# Active Biotech's project ANYARA will be presented at the European Cancer Congress 2013

## Detailed analysis further supports effect of ANYARA in a biomarker defined subgroup

**Lund (Sweden), September 12, 2013.** Active Biotech (NASDAQ OMX NORDIC: ACTI) today announced that a biomarker trend analysis of overall survival (OS) and Progression Free Survival (PFS) from the ANYARA Phase II/III study in renal cell cancer will be presented at the scientific conference "European Cancer Congress 2013" (ECCO-ESMO-ESTRO) held in Amsterdam, the Netherlands, September 27 - October 1.

Professor Tim Eisen, Department of Oncology, Cambridge University Hospitals NHS Foundation Trust, UK, will present "**Baseline biomarker trend analysis of a randomized phase 2/3 study of naptumomab estafenatox plus IFN- $\alpha$  vs IFN- $\alpha$  in advanced renal cell carcinoma** \*".

The detailed analysis gives further support to the previous findings that low baseline levels of pre-formed antibodies against ANYARA or low levels of the cytokine IL-6, independently predict anti-tumor efficacy after ANYARA+IFN- $\alpha$  treatment. The results also highlight the potential role of IL-6 as a predictive factor for the outcome of immunotherapy of cancer in general.

The analysis showed clear trends of increased OS (decreasing Hazard Ratios, "HR"s) in patients with decreasing IL-6 and anti-ANYARA antibodies. Similar trends were seen for PFS HRs.

For more detailed information, please see <http://eccamsterdam2013.ecco-org.eu/>. The presentation will be available on Active Biotech's web site [www.activebiotech.com](http://www.activebiotech.com).

\* *T. Eisen, G. Hedlund, G. Forsberg, Ö. Nordle, R. Hawkins.*

### **ABOUT THE ANYARA PHASE II/III STUDY**

The Phase II/III study encompassed 513 patients from approximately 50 sites in Europe (UK, Ru, Uk, Bu, Ro) and was designed to evaluate the effect of ANYARA (naptumomab estafenatox) in combination with interferon-alpha, compared with interferon-alpha alone, in patients with advanced renal cell cancer. The primary endpoint was overall survival (OS). Secondary endpoints were Progression Free Survival (PFS) and safety. The results were presented at ASCO in June 2013. High baseline levels of pre-formed antibodies against superantigens were shown to decrease ANYARA levels while the biomarker IL-6 was suggested to be a predictive marker for immune therapies. Although the study did not achieve its primary endpoint to show a prolonged OS in the overall ITT population, the addition of ANYARA to interferon-alpha improves OS and PFS in a biomarker defined subgroup. In this subgroup, patients with high levels of pre-formed antibodies against superantigens or the cytokine IL-6 were excluded. In this subgroup of 130 patients, the median OS for the ANYARA vs. placebo treatment arm were 63.3 vs. 31.1 months (HR: 0.59; p=0.020), respectively. The median PFS were 13.7 (ANYARA) vs. 5.8 (placebo) months (HR: 0.62; p=0.016).

### **ABOUT ANYARA**

ANYARA is a TTS (Tumor Targeting Superantigen) compound that makes the treatment of cancer tumor-specific. The development of ANYARA is mainly focused on renal cell cancer. Positive data was reported

from clinical Phase I trials in lung cancer, renal cell cancer and pancreatic cancer. In July 2009, the results from two Phase I studies of ANYARA were published in the Journal of Clinical Oncology, where ANYARA was studied both as a single agent (monotherapy) and in combination with an established tumor therapy – docetaxel (Taxotere®) – in patients with advanced cancer. The results showed that ANYARA was well tolerated both as monotherapy and in combination with docetaxel. ANYARA has been granted orphan-drug status by the EMA for the indication renal cell carcinoma.

#### **ABOUT RENAL CELL CARCINOMA**

Renal Cell Carcinoma (RCC) affects approximately 180,000 people worldwide each year. Approximately 50 % of the patients are affected by metastases. If the disease has metastasized, average survival is around 2 years. The survival rate of patients diagnosed with renal cancer is only 5-15% after five years. The market for treatment of RCC is estimated at approximately USD 2.7 billion per year (EvaluatePharma March 2012).

#### **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, tasquinimod for prostate cancer and ANYARA primarily for the treatment of renal cell cancer. In addition, laquinimod is also in Phase II development for Crohn's and Lupus. The company also has one additional project in clinical development, the orally administered compound paquinimod (57-57) for systemic sclerosis. Please visit [www.activebiotech.com](http://www.activebiotech.com) for more information.

#### **For further information:**

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#### ***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 10:00 am CET on September 12, 2013.*