Results from Active Biotech's Phase II/III ANYARA trial for the treatment of renal cell cancer

• The primary endpoint – to show a survival advantage in the intention to treat (ITT) population - was not reached.
• In a subgroup analysis, patients with low/normal baseline IL-6 and expected anti-superantigen antibody levels demonstrated proof of concept with ANYARA treatment comprising both a significantly prolonged overall survival (OS; p=0.02, HR=0.59) and Progression Free Survival (PFS).

Lund, Sweden, January 28, 2013 – Active Biotech (NASDAQ OMX NORDIC: ACTI) announced today the initial results from the ANYARA Phase II/III clinical study. The study encompassed 513 patients and was designed to evaluate the effect of ANYARA in combination with interferon-alpha, compared with interferon-alpha alone, in patients with advanced renal cell cancer. The primary endpoint was overall survival (OS).

The results showed that the ANYARA Phase II/III study did not achieve its primary endpoint to show a prolonged OS in the ITT population. Unexpectedly, and in contrast to previous studies in other territories, a majority of the patients in the current study had high levels of pre-formed antibodies against the superantigen component of ANYARA. A subgroup analysis, excluding patients with high levels of pre-formed antibodies, resulted in a trend for survival benefit with ANYARA treatment. Furthermore, baseline levels of the biomarker IL-6 was shown to be an important predictive marker for a positive treatment effect of ANYARA.

In a hypothesis generating subgroup analysis, the 25 % of patients with low/normal levels of base line IL-6 and expected anti-superantigen antibody levels, showed a statistically significant treatment advantage on both OS (p=0.02, HR=0.59) and PFS. In North America and Western Europe, this subgroup account for 40-50% of the total number of advanced renal cell cancer patients.

"The presence of pre-formed antibodies in a high number of patients was unexpected and we are disappointed that the primary endpoint of this trial was not reached. However, there is a treatment effect in a significant subgroup of patients, and this observation is congruent with ANYARAs mode of action" said Tomas Leanderson, President & CEO Active Biotech. *"Based on these data, we will seek a partner for the continued development of this unique, targeted, immune therapy".*

The safety profile was good and in line with previous observations; the most common adverse events associated with ANYARA treatment were grade 1-2 fever, nausea or vomiting. No new and unexpected safety concerns were identified in the study.

Additional analyses of the ANYARA Phase II/III study data are ongoing, and results will be submitted for presentation at a scientific congress later in the year. The company will also discuss future development strategies with major regulatory authorities.

ABOUT THE ANYARA PHASE II/III STUDY
The Phase II/III study was designed to evaluate the effect of ANYARA in combination with interferon-alpha, compared with interferon-alpha alone, in patients with advanced renal cell cancer. The primary endpoint was overall survival (OS). In May 2008, a positive interim analysis of safety and efficacy was performed and the study continued into the Phase III part. Enrollment of 513 patients was completed in June 2009 and recruited patients from approximately 50 sites in Europe (UK, Ru, Uk, Bu, Ro). Secondary endpoints in the study were Progression Free Survival (PFS) and safety.

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. Half of 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). Approved first line treatments are Sutent, Avastin + IFN, Torisel and Votrient. Approved for second line treatment are Nexavar and Everolimus.

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 for more information.

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