

New data to be presented at the 2013 ASCO Annual Meeting show Active Biotech's commitment to oncology research

Lund, Sweden, May 16, 2013, Active Biotech (NASDAQ OMX NORDIC: ACTI) will present data from two of its oncology projects, the drug candidates tasquinimod for the treatment of prostate cancer and ANYARA for the treatment of renal cell cancer, at the scientific conference "2013 ASCO Annual Meeting" to be held in Chicago (USA) on May 31- June 4, 2013. Active Biotech's collaboration partner Ipsen will present two tasquinimod posters.

Active Biotech presentations include:

- (P3073) **A randomized phase II/III study of naptumomab estafenatox plus IFN- γ versus IFN- γ in advanced renal cell carcinoma.** R. Hawkins, M. Gore, Y. Shparyk, V. Bondar, O. Gladkov, T. Ganev, M. Harza, S. Polenkov, I. Bondarenko, P. Karlov, O. Karyakin, R. Khasanov, G. Hedlund, G. Forsberg, O. Nordle, T. Eisen. The study did not achieve its primary endpoint. However, in a 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 Overall Survival (OS) and Progression Free Survival (PFS). OS was 63.3 months for the ANYARA group vs. 31.1 months for placebo group ($p=0.02$, HR=0.59) and PFS 13.7 vs. 5.8 months ($p=0.016$, HR=0.62).

- (P5081) **An Association of bone scan index (BSI) with prognostic biomarkers and survival in men with metastatic castration-resistant prostate cancer (mCRPC) enrolled in a prospective randomized controlled trial of tasquinimod.** A.J. Armstrong, R. Kaboteh, M.A. Carducci, J-E Damber, W. M. Stadler, M.Hansen, L. Edenbrandt, G. Forsberg, O. Nordle, R. Pili, M. J. Morris. The Bone Scan Index (BSI) was prognostic for OS in mCRPC patients enrolled in the Phase II multicenter trial of tasquinimod and treatment with tasquinimod was associated with a decreased BSI progression rate. This study is co-sponsored by Active Biotech, Exini and Ipsen.

Ipsen presentations on tasquinimod include:

- (P5098) **A Randomized, double-blind, placebo-controlled proof of concept study of tasquinimod maintenance therapy in patients with metastatic castrate-resistant prostate cancer (mCRPC) who experience response or stabilization during first-line docetaxel chemotherapy.** K Fizazi, A Heidenreich, G Daugaard, J Bellmunt, N Germann, E Chetaille. This Phase II, multinational, randomized, double-blind, placebo-controlled proof of concept study is on-going. It is performed and sponsored by Ipsen. Patients with mCRPC will be randomly assigned (ratio 1:1) to receive tasquinimod or placebo. Randomization will be stratified by presence of visceral metastases and opioid analgesic use for cancer-related pain.

- (P2622) **A Phase II, multicenter, open-label, proof of concept study of tasquinimod in patients with advanced/metastatic hepatocellular (HCC), ovarian (OC), renal cell (RCC) and gastric (GC) carcinomas.** B Escudier, S Faivre, A Oza, E Van Cutsem, A Geniaux, F Baton. This Phase II, multinational, exploratory proof of concept study performed and sponsored by Ipsen, will evaluate tasquinimod activity in four independent cohorts of patients (HCC, OC, RCC and GC) with progressive disease after standard therapy. An innovative design based on the proportion of patients who have not progressed nor died at predefined time points (PFS rate) will be used in each cohort independently.

For more detailed information, please see www.asco.org.

A global, pivotal, randomized, double-blind, placebo-controlled Phase III study of tasquinimod in patients with asymptomatic to mildly symptomatic metastatic CRPC who have not yet received chemotherapy is ongoing. The aim of the study is to confirm tasquinimod's efficacy, with



radiological Progression Free Survival (PFS) as primary endpoint and overall survival (OS) as key secondary endpoint. The study recruited 1, 245 patients in 37 countries covering more than 200 centers.

Notes to editors

About ANYARA

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

In January 2013, the initial results were presented 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. A subgroup analysis, comprising about 25 percent of the 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 progression-free survival (PFS). In North America and Western Europe, this subgroup accounts for approximately 40-50% of the total number of advanced renal cell cancer patients. The safety profile was favorable and in line with that observed earlier. Active Biotech plans to continue the development of ANYARA jointly with a partner after completed analysis of study data and discussions with relevant authorities.

About tasquinimod

Tasquinimod is a novel small molecule that targets the tumor microenvironment by binding to S100A9 and modulating regulatory myeloid cell functions, exerting immunomodulatory, anti-angiogenic and anti-metastatic properties. Tasquinimod may also suppress the tumor hypoxic response, contributing to its effect on the tumor microenvironment. 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. The results showed that six month progression free proportion of patients for tasquinimod 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, showed 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. In June, 2012, overall survival (OS) data was presented at ASCO (American Society of Clinical Oncology).

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 in Phase II development for Crohn's and Lupus. The company also has one additional compound in clinical development, the orally administered compound paquinimod (57-57) for systemic sclerosis. Please visit www.activebiotech.com for more information.

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