



**PRESS RELEASE**

**Active Biotech's TASQ prostate cancer project  
presented at ASCO**

**Lund, Sweden, June 7, 2010** - Active Biotech AB's (NASDAQ OMX Nordic:ACTI) prostate cancer project TASQ has been presented at the scientific conference 46th Annual Meeting of the American Society of Clinical Oncology (ASCO) held in Chicago, June 4-8, 2010.

The presentation included data from a randomized placebo-controlled double blind clinical Phase II study of TASQ - an oral antiangiogenic agent with S100A9 as a molecular target - in patients with asymptomatic metastatic castrate-resistant prostate cancer (CRPC).

The primary endpoint, to show a difference in the number of patients with disease progression at six months, was, as previously reported, reached. Updated results showed that the fraction of patients with disease progression during the six month period was 31% for patients treated with TASQ compared to 66% for placebo treated patients ( $p < 0.0001$ ). The median progression free survival was 7.6 months for the TASQ group, compared to 3.2 months for the placebo group ( $p = 0.0009$ ). TASQ treatment also had an effect on biomarkers relevant for prostate cancer progression and was generally well tolerated.

"I believe the results on the inhibition of disease progression are clinically significant. This is the first controlled trial to demonstrate an improvement in median progression-free survival using the Prostate Cancer Working Group-2-defined radiological criteria", says coordinating investigator Roberto Pili, Professor of Oncology and Co-Leader of the Genitourinary Program at the Roswell Park Cancer Institute. "I am also pleased to see that TASQ appears to be well tolerated in this group of asymptomatic patients".

"With its pronounced anti-metastatic effect and unique mode of action, TASQ has the potential to be a valuable treatment for patients with advanced prostate cancer. I look forward to the continued development of TASQ into Phase III clinical trials and in combination studies", says co-author Andrew Armstrong, MD ScM, Assistant Professor of Medicine and Surgery at Duke University and the Duke Prostate Center.

For more detailed information, please see [www.asco.org](http://www.asco.org).

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## Notes to editors

### About the TASQ Phase II study

The reported clinical trial is a 2:1 randomized, placebo controlled, double-blind Phase II trial investigating 1 mg/day of TASQ (tasquinimod, ABR-215050) versus placebo in 206 asymptomatic patients with metastatic, castrate resistant, prostate cancer. The trial was conducted in the US, Canada and Sweden under an IND (Investigational New Drug) application.

The primary endpoint of the Phase II trial was to measure the proportion of patients that display disease progression after six months of TASQ therapy compared with placebo. Secondary clinical endpoints of importance for this group of patients include progression free survival, safety and effects on biomarkers. Documentation of such endpoints is of importance for future TASQ development and registration.

The primary endpoint, to show a difference in the number of patients with disease progression at six months, was reached. The fraction of patients with disease progression during the six month period was 31% for patients treated with TASQ compared to 66% for placebo treated patients. The median progression free survival was 7.6 months for the TASQ group, compared to 3.2 months for the placebo group ( $p=0.0009$ ). Central review of the scans support an effect on PFS with TASQ treatment with a median PFS of 8.4 months for TASQ treated patient versus 3.8 months for the placebo patients ( $p=0.0045$ ).

Sub-group analysis using the PCWG2 (Prostate Cancer Clinical Trials Working Group 2) defined criteria showed that mPFS (median Progression Free Survival) for patients with visceral (soft tissue, for example lung or liver) metastases was 6.0 months for the TASQ treated group compared to 3.0 months for the placebo group ( $p=0.0160$ ). For patients with only bone metastases, mPFS was 12.2 (TASQ) versus 5.4 months (placebo) ( $p=0.0214$ ).

Patients with soft tissue lesions were analyzed using RECIST disease progression criteria. Tumor shrinkage was observed 15/65 patients (23 %) in TASQ and 5/42 patients (12 %) in the placebo group. Partial responses (i.e. tumor shrinkage of 30 % or more) were observed in 6 % of the TASQ treated patients, while no objective responses (measurable responses) were observed in the placebo group.

Analysis of secondary clinical endpoints such as biomarkers show:

- TASQ treatment had a minor effect on PSA
- VEGF levels increased with 23 % (TASQ) vs. 1 % decrease (placebo) at 3 months
- BAP levels decrease 6 % (TASQ) vs. 24 % increase (placebo) at 3 months

Most common AEs were GI problems like nausea, constipation or decreased appetite and fatigue. Majority of AEs were of grade 1 and 82 % of grade 3-5 AEs were of grade 3. Using a dose escalation strategy, TASQ was generally well tolerated at individualized dose levels.

### About TASQ

TASQ binds to a molecule called S100A9 which is expressed in some 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 principally focused on the treatment of [prostate cancer](#). TASQ is an antiangiogenic compound, meaning that it cuts off the supply of nutrients to the tumor but it does not belong to the most frequently occurring group of tyrosine kinase inhibitors. Up-regulation 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).

A phase III trial of TASQ in patients with asymptomatic metastatic castrate-resistant prostate cancer is currently in preparation.

#### **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, as well as ANYARA for use in cancer targeted therapy, primarily of renal cancer. Further key projects in clinical development comprise the three orally administered compounds TASQ for prostate cancer, 57-57 for SLE and RhuDex™ for RA. Please visit [www.activebiotech.com](http://www.activebiotech.com) for more information.

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