



Orphan Medicinal Product Status to Active Biotech's 57-57 project recommended

Lund, Sweden, November 18, 2010 - Active Biotech AB (NASDAQ OMX Nordic:ACTI) today announced that the COMP (Committee for Orphan Medicinal Products) adopted a positive opinion recommending the project 57-57 for designation as orphan medicinal product, for the indication Systemic Sclerosis (SSc), to the European Commission.

Preparations are in progress for the launch of an explorative study in Systemic Sclerosis during 2011.

Active Biotech AB (publ)

Tomas Leanderson
President and CEO

About EMA's Orphan Medicinal Product Designation

The EMA's "Orphan Medicinal Product Designation" is implemented to promote the development of drugs which may provide significant benefit to patients suffering from rare diseases identified as life-threatening or chronically debilitating. Under EMA guidelines, Orphan Medicinal Product Designation provides 10 years of potential market exclusivity if the product candidate is approved for marketing in the European Union. Orphan status also permits EMA assistance in optimizing the candidate's clinical development through participation in designing the clinical protocol and preparing the marketing application. Additionally, a drug candidate designated by the EMA as an Orphan Medicinal Product may qualify for a reduction in regulatory fees as well as a European Union-funded research grant.

About 57-57

57-57 is an orally active small molecule which binds to the molecule S100A9 and blocks its interaction with the pro-inflammatory receptors RAGE and TLR4. 57-57 interferes with early stage of immune activation and acts immunomodulatory without causing general immune suppression. Excellent properties for oral once daily administration has been demonstrated.

Phase I studies and a small-scale exploratory clinical study of 57-57 in SLE patients have been conducted. This study has recently been completed. In August 2010, the company decided to initiate the development of 57-57 for the treatment of Systemic Sclerosis.

About Systemic Sclerosis

Systemic sclerosis (SSc) is a rare autoimmune disease. SSc is characterized by disturbances of the immune system and by overproduction and deposition of various proteins in particular collagen leading to inflammation and abnormal growth of the connective tissue of the skin and internal organs such as gastrointestinal tract, lungs, heart and kidney. The disease may lead to severe dysfunction and can be life threatening due to failure of internal organ.



There is presently no cure for SSc and existing treatments are focused on controlling symptoms and preventing complications. There is a high unmet medical need for new targeted therapies of SSc.

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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 as well as 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 & Systemic Sclerosis and RhuDex™ for RA. Please visit www.activebiotech.com for more information.

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 November 18, 2010 at 10:00 am.

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