FDA GRANTS ORPHAN DRUG DESIGNATION FOR TASQUINIMOD IN MYELOFIBROSIS

Lund, May 18, 2022 - Active Biotech (NASDAQ STOCKHOLM: ACTI) today announced that the U.S. Food and Drug Administration (FDA) has granted tasquinimod Orphan Drug Designation for the treatment of myelofibrosis.

"The Orphan Drug Designation awarded by the FDA for tasquinimod in myelofibrosis represents an important step forward for Active Biotech", said Helén Tuvesson, CEO Active Biotech. "It opens an important regulatory pathway and provides us with the potential to rapidly advance the development of tasquinimod in this patient population."

The FDA Orphan Drug Designation program provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnoses or prevention of rare diseases or disorders that affects fewer than 200,000 people in the U.S. This designation provides for a seven-year marketing exclusivity period against competition, as well as certain incentives.

In February 2022, Active Biotech entered into an exclusive license agreement with Oncode Institute in the Netherlands, acting on behalf of Erasmus University Medical Center (Erasmus MC), Rotterdam, for the global rights to patents relating to the use of tasquinimod in the treatment of myelofibrosis.

Active Biotech and Erasmus MC have initiated a research collaboration with tasquinimod in myelofibrosis, that includes preclinical studies as well as a clinical proof of concept study in patients with myelofibrosis. The clinical study will be financed by Oncode and is planned to start early 2023.

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This information is information that Active Biotech AB is obliged to make public pursuant to the EU Market Abuse Regulation. This information was submitted for publication, through the agency of the contact person set out above, at 15:00 pm CET on May 18, 2022.

About tasquinimod
Tasquinimod is an oral immunomodulatory and anti-angiogenic investigational treatment, that affects the tumor's ability to grow and metastasize. Tasquinimod is developed as a new immunomodulatory treatment for hematological malignances, in the first step multiple myeloma. Tasquinimod has previously been studied as an anti-cancer agent in patients with solid cancers, including a phase III randomized trial in patients with metastatic prostate cancer. The tolerability of tasquinimod is well-characterized based on these previous experiences. Tasquinimod has demonstrated a clear therapeutic potential in preclinical models of multiple myeloma, when used as a single agent and in combination with standard multiple myeloma therapy. A clinical Phase Ib/IIa study is ongoing with tasquinimod in relapsed or refractory multiple myeloma.

About Myelofibrosis

Myelofibrosis (MF) is a rare blood cancer belonging to a group of disorders called myeloproliferative neoplasms. The underlying cause of MF is unknown. The estimated annual incidence of MF is 0.4 - 1.3 cases per 100 000 people in Europe. Patients with MF have an abnormal production of blood-forming cells leading to the replacement of healthy bone marrow with scar tissue (fibrosis). Due to the lack of normal blood cell production patients typically present with laboratory value abnormalities such as anemia and changes in white blood cell counts and blood cell -differentiation. Later symptoms include enlargement of the spleen, an increased risk for infections, night sweats and fever. MF is associated with shortened survival and causes of death include bone marrow failure and transformation into acute leukemia. MF can be treated with bone marrow transplantation for eligible individuals, erythropoietin to manage anemia and JAK inhibitors to reduce spleen size. At present there are no approved therapies that would reverse bone marrow fibrosis in MF.

Active Biotech AB (publ) (NASDAQ Stockholm: ACTI) is a biotechnology company that deploys its extensive knowledge base and portfolio of compounds to develop first-in-class immunomodulatory treatments for specialist oncology and immunology indications with a high unmet medical need and significant commercial potential. Following a portfolio refocus, the business model of Active Biotech aims to advance projects to the clinical development phase and then further develop the programs internally or pursue in partnership. Active Biotech currently holds three projects in its portfolio: The wholly owned small molecule immunomodulators, tasquinimod and laquinimod, both having a mode of actions that includes modulation of myeloid immune cell function, are targeted towards hematological malignancies and inflammatory eye disorders, respectively. Tasquinimod, is in clinical phase Ib/IIa for treatment of multiple myeloma. Laquinimod is in a clinical phase I study with a topical ophthalmic formulation, to be followed by phase II for treatment of non-infectious uveitis. Naptumomab, a targeted anti-cancer immunotherapy, partnered to NeoTX Therapeutics, is in a phase Ib/II clinical program in patients with advanced solid tumors. Please visit www.activebiotech.com for more information.