



PRESS RELEASE

Active Biotech announces new direction

Lund Sweden, February 5, 2020 - Active Biotech (NASDAQ STOCKHOLM: ACTI) announces that the Board of Directors, has approved a new direction for the company. This decision follows a detailed opportunity analysis of the company's wholly owned clinical lead assets, laquinimod and tasquinimod. Based on assessment of the many scientific publications and extensive pre-clinical and clinical data accumulated, an analysis of the commercial attractiveness of different clinical indication opportunities to Active Biotech, as well as an external advisory challenge, new focused target indications and corporate priorities have been defined.

Tasquinimod will be advanced in a new academic partnership, as an immunomodulatory product with a novel mechanism of action, for the treatment of multiple myeloma. Laquinimod will be advanced, as an immunomodulatory product with a novel mechanism of action, for use as a topical agent in inflammatory eye diseases and as an oral treatment of patients with Crohn's disease.

Going forward, Active Biotech has a project portfolio comprising naptumomab, partnered to NeoTX and currently in Phase 1b/2 for the treatment of advanced solid tumors, and the new clinical and pre-clinical programs for tasquinimod and laquinimod.

No further work on the prior clinical programs within multiple sclerosis or Huntington's disease for laquinimod or solid tumors for tasquinimod will be undertaken. In addition, Active Biotech will for now put on hold the paquinimod and SILC-projects, to create a clear focus on the prioritized activities, and no further communication in relation to these assets is expected.

Opportunity analysis and new pipeline projects

Over the past 6 months, we have undertaken a detailed evaluation of tasquinimod and laquinimod from a technical as well as a commercial perspective, to assess potential value-enhancing paths forward for the company in developing these assets. The analyses included updated scientific insights on the mechanism of action of the compounds, as well as analyses of how best to leverage the existing clinical safety data. A broad network of international expert advisors has been engaged in this process, to ensure adequate external challenge of ideas and directions developed. The new indications now being advanced for tasquinimod and laquinimod represent diseases with significant unmet medical need and commercial potential where IP has been secured or filed.

The new project portfolio comprises potential high-value indication opportunities for which pre-clinical efficacy and safety results, in addition to a comprehensive CMC documentation, already has been generated. The company's new strategy aims at advancing the projects in well-defined focus areas by leveraging existing results in combination with smaller proof-of-concept or confirmatory phase 2 studies to enable early and cost-effective value crystallization to Active Biotech through partnering/out-licensing.

- Tasquinimod will be advanced as a new product for treatment of multiple myeloma

Based on our analysis and ongoing business development activities, we today announce the formation of an academic partnership with The Perelman School of Medicine, University of Pennsylvania for the development of tasquinimod as a new immunomodulatory product for the treatment of multiple myeloma. Extensive preclinical studies performed in collaboration with the Wistar Institute in Philadelphia, during the past 24 months, provide clear support for the advancement of tasquinimod in multiple myeloma, these data will be published in peer-reviewed journals. The parties are preparing to initiate a phase 1b/2a study in Q2-2020 and expect the first patient treated in Q3-2020. This program has also received funding from the Leukemia & Lymphoma Society in United States.

- *Laquinimod as a new product for use in eye disorders*

Our analyses have revealed an exciting pre-clinical evidence base supporting use of laquinimod for treatment of the two eye disorders Wet AMD and Uveitis which has not yet been published. Our focus the coming 12 months will be, on a pre-clinical study basis, to increase our understanding of the therapeutic potential of laquinimod through additional pre-clinical studies, and to define how best to develop laquinimod as a topical agent within these diseases, as suggested from the initial pre-clinical data.

- *Laquinimod as a new product in Crohn's disease*

We have also decided to advance laquinimod for use in Crohn's disease, as an immuno-modulatory agent with a novel mechanism of action, an indication for which a prior clinical Phase 2a study provides compelling data. Our review of the extensive preclinical scientific profiling of laquinimod in models of gastro-intestinal disorders, further supports a potential role in treatment of Crohn's disease. We will during the coming 12 months refresh the prior regulatory advice received from the FDA, and explore possible partnership modalities, including academic partnerships, to advance the evaluation of laquinimod in this indication.

"After a comprehensive analysis of our project portfolio, we are now advancing our lead projects in a new direction to maximize the value creation opportunity for Active Biotech. We are very enthusiastic about developing laquinimod and tasquinimod further in these new indications with unmet medical need and where existing data can be optimally used" says *Helén Tuve*sson, CEO of Active Biotech. "The commercial value that each of these indications represents is substantial, and our focus is to realize this in a cost-effective manner leveraging academic partnerships and our network", continues Helén Tuvesson.

Financial impact

At year-end 2019 available cash is scheduled to finance ongoing activities in the new direction through 2021. In addition, Active Biotech is evaluating corporate development opportunities to broaden the shareholder base, and to strengthen the project portfolio.

"The extensive scientific profiling, and prior investments into large clinical programs for laquinimod and tasquinimod, now enables a faster and more focused development of these projects for different clinical applications. We have leveraged this substantial evidence base in a structured manner to support setting our portfolio priorities, and look forward to executing on this new directions" says *Michael Shalmi*, Chairman of the Board of Active Biotech.

In conjunction with the Annual General Meeting of Active Biotech in May, the company will invite interested parties to join a separate Investor Session, in which the medical need and scientific support of the plans and activities now defined for tasquinimod and laquinimod, will be presented. Further details will be communicated later.

About tasquinimod and laquinimod

Laquinimod, is an orally administered small molecule with unique immunomodulatory properties that previously has been developed primarily within neurodegenerative diseases. Tasquinimod is an immunomodulatory and anti-angiogenic compound, primarily studied in solid cancer indications, that affects the tumor's ability to grow and spread. During its years of advanced product development, clinical efficacy and safety data on laquinimod and tasquinimod was established in more than 5000 and 1500 patients, representing more than 14000 and 650 patient-years of exposure, respectively. In addition, extensive datasets spanning full-scale manufacturing and pre-clinical safety data, in support of regulatory filings of multiple sclerosis for laquinimod and advanced prostate cancer for tasquinimod, has also been generated

About multiple myeloma

Multiple myeloma is an incurable blood cancer in which abnormal plasma cells in the bone marrow grow uncontrollably while other blood forming cells such as white and red blood cells and blood platelets are suppressed. This leads to anemia, infections, destruction of bone tissue and progressive loss of renal function. Despite new treatments have greatly improved survival of multiple myeloma patients, the biological heterogeneity of the disease and the emergence of drug resistance is a major challenge, and the medical need of innovative treatment modalities remains high.

In 2017, 81000 new cases of multiple myeloma were diagnosed in the eight major markets. The global sales* of drugs for multiple myeloma totaled USD 16 billion in 2017 and sales are expected to increase 48% by 2026.

About age-related macular degeneration and uveitis

Age-related macular degeneration (AMD) is caused by damage to the macula or retina, which results in blurred or loss of vision in the center of the visual field and the leading cause of blindness in the Western world. In the neovascular AMD, the "wet" form of advanced AMD (wAMD), abnormal blood vessel growth in the eye leads to vision loss. Bleeding, leaking and scarring from these vessels cause irreversible damage and retinal detachment. About 10-20 % of late-stage AMD cases progress into wAMD, and is responsible for 90% of acute blindness due to age-related macular degeneration. Standard of care of wAMD is frequent invasive intravitreal injections of antibodies targeting the vascular endothelial growth factor (VEGF). However, even with these therapies, there is a great unmet need of new effective treatments with less invasive and more convenient delivery modalities.

Around 3 million people in the seven major markets were estimated to have wAMD in 2018. The global sales* of drugs for wAMD totaled USD 6.3 billion in 2018 and sales are expected to increase 67% by 2026.

Uveitis is the inflammation of the uveal tract (iris, ciliary body, & choroid), but can also cause inflammation of nearby tissues, such as the retina, the optic nerve and the vitreous humor. General vision problems, floaters-spots in the eye, eye pain and redness, photophobia, headache, small pupil, alteration of iris color are common symptoms. If left untreated, uveitis can lead to severe eye problems, including blindness, cataracts, glaucoma, damage to the optic nerve, and detachment of the retina. In non-infectious uveitis there is a need for new therapies to avoid the abundant complications of long-term corticosteroid use.

Around 1 million people in the seven major markets were estimated to have uveitis in 2017. The global sales* of drugs for uveitis totaled USD 615 million in 2017 and sales are expected to increase 70% by 2026.

About Crohn's disease

Crohn's disease is an autoimmune disease, in which the autoimmune activity produces inflammation in the gastrointestinal tract and is classified as an inflammatory bowel disease (IBD). The symptoms of the disease can vary significantly among afflicted individuals. The main gastrointestinal symptoms are abdominal pain, diarrhea, or weight loss. Crohn's disease can also cause complications outside of the gastrointestinal tract such as skin rashes, arthritis, and inflammation of the eye. Although treatment with pharmaceutical agents and/or surgery can lead to clinically significant improvements in Crohn's disease, relapse is the major problem and therefore the maintenance of tissue healing remains the key challenge.

During 2018 the number of treated patients with Crohn's disease in the seven major markets amounted to approximately 0,5 million. The global sales* of drugs for Crohn's disease totaled USD 12.4 billion in 2018 and sales are expected to increase 32% by 2026.

* As estimated by Global Data



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Active Biotech AB (publ) (NASDAQ Stockholm: ACTI) is a biotechnology company with focus on autoimmune/inflammatory diseases and cancer. Please visit www.activebiotech.com for more information.

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