

PRESS RELEASE

Active Biotech fulfills important milestone for the SAIK-MS project

The clinical Phase 1 study on Active Biotech's SAIK-MS compound, ABR-215062 in healthy volunteers and MS patients is concluded.

The study has successfully reached its clinical endpoint, and has provided the future clinical development programme with valuable information.

A million people worldwide are affected by multiple sclerosis (MS), a chronic autoimmune disease. The body's own immune defence attacks the insulating myelin sheaths surrounding the nerve fibres in the central nervous system, thereby disrupting or discontinuing the nerve impulses. The disease has a slow, drawn-out cycle and often occurs in spells with alternating periods of improvement and deterioration.

There is currently no treatment to halt MS, although beta interferon injections has been demonstrated to slow the disease in some patients. Active Biotech has selected a new treatment strategy with its SAIK immunomodulators, which also have the advantage of being available in tablet form.

The study now concluded was designed as a dose escalation study with the objective to document safety of the compound in humans. In the first part of the study, healthy volunteers in groups of 5 (of which 1 received placebo), were treated for five consecutive days with escalating doses from 0.05 mg up to 2.4 mg/day. All treatments were well tolerated and there were no treatment related clinically important changes in laboratory safety parameters.

Subsequently, MS patients (6 patients/group, 1 placebo) were included and treated for four weeks. At the starting dose, 1.2 mg/day, treatment was, also in this part of the study, well tolerated and no treatment related clinically important changes in laboratory safety parameters could be registered.

Among the group of MS-patients that received the highest dose (2.4 mg/day), all treated patients showed increases in laboratory parameters indicating inflammatory activity. The reactions observed were remarkably uniform with respect to degree and time spent after the first dose. We regard this uniform result as very positive. According to the clinical protocol, such increases in 2 or more patients is defined as dose limiting toxicity. Thus, the study has met its endpoint and the Maximal Tolerable Dose (MTD) in MS patients is defined as 1.2 mg/day, i.e. the highest dose at which there are no measurable negative changes in safety parameters.

The defined MTD is in good agreement with the predictions calculated from pre-clinical safety data. According to these calculations, the therapeutic dose-response range of the SAIK-MS substance in MS patients can be expected to be 0.03 – 0.3 mg/day, i.e. well below the MTD, which means a considerably large safety margin with respect to toxicity.

Totally the study comprised of 35 healthy volunteers and 11 MS patients.

The next step in the development of the SAIK-MS product is now to prepare for and perform a clinical Phase 2 study designed to show “clinical proof of concept” in a larger group of MS patients, i.e. to demonstrate that SAIK-MS has therapeutic activity on the disease multiple sclerosis.

Active Biotech has previously communicated the ongoing discussions with potential business partners regarding clinical development and future marketing of SAIK-MS. Active Biotech will proceed with these discussions, with no delay in the preparations and work with the Phase II study. A collaboration with a partner will only be initiated if and when Active Biotech finds that the agreement terms corresponds to the company's estimated value of the project.

The results from the concluded Phase I study are very promising and valuable. However, extensive development work and trials need yet to be performed before an approval of a product for the treatment of MS can be achieved from the authorities, and for the medicine to reach patients.

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Active Biotech AB (Publ)

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***Active Biotech AB** is a biotechnology company focusing on research and development of medicines and vaccines. Our expertise lies in the knowledge of the human immune defence system. We have a high-quality project portfolio and financial strength. The most important products and projects are medicines for multiple sclerosis (SAIK) and cancer (TTS), the SBL Cholera Vaccine, and Dukoral and ETEC vaccines against tourist diarrhoea. Active Biotech's turnover was MSEK 280 in 2000.*

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