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AB Science announces recruitment of first patient in phase 2B/3 study of masitinib in rheumatoid arthritis

AB Science SA (NYSE Euronext - FR0010557264 - AB), a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), announced today the recruitment of the first patient in the phase 2b/3 study of masitinib in rheumatoid arthritis.

This is an international, multicenter, randomized, double-blind, placebo-controlled, 3-parallel groups, phase 2b/3 study. Its objective is to compare the efficacy and safety of masitinib at 3 and 6 mg/kg/day to methotrexate in the treatment of patients with active rheumatoid arthritis with inadequate response to: i) methotrexate; ii) any Disease-modifying anti-rheumatic drug (DMARD) including at least one biologic drug if patients previously failed methotrexate; or iii) methotrexate in combination with any DMARD including biologic drugs. This study will enroll approximately 450 patients, across 90 centers around the world. The primary response evaluation will be the proportion of patients to achieve an improvement of at least 50% in their symptoms (ACR50) after 24 weeks of treatment.

Professor Jacques Tebib (Hôpital Lyon-Sud, France) the principal investigator of this study declared: "Masitinib is a selective inhibitor of c-Kit and Lyn. These are two kinases that play a major role in the survival and activation of mast cells, which are cells involved in the immune response and also a key component of the inflammatory processes associated with rheumatoid arthritis and many of its resulting symptoms. It is possible that masitinib's inhibitory action also effects the activation of certain other immune cells, for example dendritic cells (which express c-Kit). Masitinib therefore represents a different approach from those oral drugs already on the market, with a unique mechanism of action that may be complementary to other products by blocking mast cells. Masitinib also differentiates itself by the fact that it may possibly be administered as a single-agent without the long-term toxicity limitations associated with methotrexate. In an experimental model of rheumatoid arthritis (transgenic mouse K / Bx TCR), masitinib demonstrated an ability to prevent the development of rheumatoid arthritis. Two phase 2 studies were conducted with a total of approximately seventy patients who were either resistant to methotrexate, or resistance to anti-TNF alpha, or resistance to both. The first study tested masitinib administered as a single-agent, and the second study tested masitinib in combination with methotrexate. Both studies showed similar and positive results. In both cases, the key evaluation parameter of at least 50% improvement in symptoms (ACR50) was achieved in 30% of patients resistant to methotrexate and also in approximately 30% of patients with resistance to anti-TNF alpha. These phase 2 results of masitinib treatment are similar to those data from the phase 3 clinical trials of anti-CD20-based therapies, which formed the basis for registration in this indication."

Professor Olivier Hermine, President of the scientific committee of AB Science commented: "Masitinib differs from those treatments currently available or under development in rheumatoid arthritis. For example, its oral administration differentiates it from commonly used biological treatments. Also, by blocking the activation of mast cells masitinib not only reduces the production of TNF but also the recruitment of other inflammatory cells, which explains its efficacy in patients resistant to anti-TNF and differentiates it from Syk inhibitors currently developed. Finally, among the tyrosine kinase inhibitors, masitinib's characteristic selectivity against mast cells means it induces little or no immunosuppressive effect, unlike the JAK inhibitors."

This phase 3 study is fully financed.

About rheumatoid arthritis

Rheumatoid arthritis is a very frequent disease affecting between 0.5% and 1% of the population, in which various joints in the body are inflamed, leading to swelling, pain, stiffness, and the possible loss of function. In rheumatoid arthritis, an abnormal autoimmune response produces destructive molecules that cause continuous inflammation of the synovium. Collagen is gradually destroyed, narrowing the joint space and eventually damaging bone. In rheumatoid arthritis, the mast cell is likely to play an important role by producing chemokines that recruit other inflammatory cells, cytokines (such as tumor necrosis factor) that cause inflammation, and also metalloproteinase that contribute to joint destruction.

About masitinib

Masitinib is a new orally administered tyrosine kinase inhibitor that targets mast cells, important cells for immunity, as well as a limited number of kinases that play key roles in various cancers. Owing to its novel mechanism of action, masitinib can be developed in a large number of conditions in oncology, in inflammatory diseases and in certain diseases of the central nervous system. Through its activity of inhibiting certain kinases that are essential in some oncogenic processes, masitinib may have an effect on tumor regression, alone or in combination with chemotherapy. Through its activity on the mast cell and certain kinases essential to the activation of the inflammatory cells and fibrosing tissue remodeling, masitinib can have an effect on the symptoms associated with some inflammatory and central nervous system diseases.

About AB Science

Founded in 2001, AB Science is a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), a new class of targeted molecules whose action is to modify signaling pathways within cells. Through these PKIs, the Company targets diseases with high unmet medical needs (cancer, inflammatory diseases and central nervous system diseases), in both human and veterinary medicines. AB Science has developed its own portfolio of molecules including masitinib, which has already been registered in veterinary medicine in Europe and in the USA, and is pursuing nine phase 3 studies in human medicine, including six studies on-going in pancreatic cancer, GIST, in metastatic melanoma expressing JM mutation of c-Kit, in mastocytosis, severe persistent asthma, and rheumatoid arthritis.

Further information is available on AB Science's website: www.ab-science.com

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