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AB Science announces recruitment of first patient in phase 3 study of masitinib in severe asthma

AB Science SA (NYSE Euronext - FR0010557264 - AB), a pharmaceutical company specialising in the research, development and commercialisation of protein kinase inhibitors (PKIs), announced today the recruitment of the first patient in the phase 3 study evaluating masitinib in severe persistent asthma.

This is an international, multicenter, randomised, double-blind, placebo-controlled, 2-parallel groups, Phase 3 study to compare the efficacy and the safety of masitinib at 6 mg/kg/day versus placebo in the treatment of patients with Severe Persistent Asthma treated with oral corticosteroids. The trial will enroll approximately 300 patients, across 60 centres around the world, randomised with a ratio 2 to 1 between the masitinib and placebo. The primary criterion will be the Asthma exacerbation rate (severe and moderate exacerbations) at 36 weeks adjusted on the available person-time (time to end of treatment).

Dr Leroyer (CHU Brest, France), principle investigator for this study declared: *«There is a high unmet medical need in this disease where patients have a poor quality of life but can also have fatal exacerbations. In phase 2, masitinib generated promising efficacy results and was considered safe in this patient population. Over 16 weeks of treatment, the exacerbation rate was reduced by 40.5% in masitinib treated group. Focusing on patients requiring above 15mg equivalent prednisone per day, 31.6% of patients were weaned from oral corticosteroids in the masitinib treatment groups at week 16 versus none in the placebo arm. An improved asthma control (ACQ7) was observed in masitinib-treated patients (+42% versus +8% in placebo group). ITT (intention to treat) analysis showed patients treated with masitinib experienced a statistically significant change from baseline in ACQ7 total score ($P < 0.001$), while the placebo group showed no statistically significant change. It is the first time an oral treatment blocking mast cells is tested in this disease in a comparative pivotal phase 3 study, and we are eager to see the outcome ».*

This phase 3 study is fully financed.

About severe persistent asthma

Asthma is a very widespread disease which affects some 200 to 300 million people the world, which is a prevalence of between 4% and 7%. For around 10% of asthmatics (severe asthma), the disease remains symptomatic despite treatment with high doses of inhaled corticosteroids and long-acting β -2 antagonists. This form of asthma is characterised by the need to take corticosteroids systemically (not inhaled). Patients frequently suffer exacerbations which can give rise to hospitalisation and are sometimes fatal. This disease affects the patients' quality of life on a lasting basis and is life threatening. Immunosuppressive drugs such as methotrexate or biological drugs such as anti tnf alpha, which are effective in other inflammatory conditions such as rheumatoid arthritis, psoriasis or crohn's disease, have failed to demonstrate efficacy in asthma.

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 tumour 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 remodelling, 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 specialising in the research, development and commercialisation of protein kinase inhibitors (PKIs), a new class of targeted molecules whose action is to modify signalling 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. Thanks to its extensive research and development capabilities, AB Science has its own portfolio of molecules. Masitinib, a lead compound, has already been registered in veterinary medicine in Europe and in the USA, and is pursuing nine phase 3 studies in human medicine, including five studies on-going in pancreatic cancer, GIST, in metastatic melanoma expressing JM mutation of c-Kit, in mastocytosis, and severe persistent asthma.

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

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