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AB Science announces that FDA authorization (IND) has been granted for the initiation of its phase 3 study in severe asthma. Patient recruitment commences in the US.

AB Science SA (NYSE Euronext - FR0010557264 - AB), a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), announced today that it has obtained IND status (Investigation New Drug – authorization to administer an investigational drug to humans) from the US Food and Drug Administration (FDA) and can now commence its phase 3 study of masitinib in severe persistent asthma in the US. This study had previously received European authorization and has therefore already commenced patient recruitment from European sites earlier this year.

This is an international, multicenter, randomized, double-blind, placebo-controlled, two-parallel groups, phase 3 study to compare the efficacy and the safety of masitinib at 6 mg/kg/day against placebo in the treatment of patients with Severe Persistent Asthma uncontrolled with oral corticosteroids.

This study, which is already recruiting patients in Europe and other countries around the world, will enroll approximately 300 patients in total.

"This IND for a phase 3 study follows an extensive review of masitinib data by the FDA in the indication referred to and reflects a favorable analysis from the FDA on the potential of masitinib to provide a suitable therapeutic solution in severe persistent asthma. For the record, severe persistent asthma uncontrolled with oral corticosteroids is a disease that has no registered treatment and all the immunosuppressant and biologic drugs tested to date have failed. Masitinib is therefore the only drug candidate in this indication. In addition, masitinib is an oral therapy and is well tolerated. This authorization from the FDA follows that of the EMA and the European countries participating in the study", said Alain Moussy, President and CEO of AB Science.

About severe persistent asthma

Asthma is a widespread disease that affects some 200 to 300 million people worldwide, corresponding to a prevalence of 4% to 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 characterized by the need to take corticosteroids systemically (not inhaled). Patients frequently suffer exacerbations that can give rise to hospitalization and are sometimes fatal. This disease has a long term negative effect on the patients' quality of life and is a life threatening condition. Immunosuppressive therapies such as methotrexate or biological drugs including 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 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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