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AB Science announces issuance of a new U.S. patent for masitinib in the treatment of severe persistent asthma that extends the protection for the use of masitinib in asthma until 2032

AB Science SA (NYSE Euronext - FR0010557264 - AB), a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), today announced that the U.S. Patent and Trademark Office has issued a Notice of Allowance for patent (13/983626) relating to methods of treating severe persistent asthma with its lead compound masitinib. This patent, which expires in 2032 protects to the use of masitinib in the treatment of severe persistent corticosteroid-dependent asthma and severe persistent corticosteroid-resistant asthma. This patent was filed based on the discoveries obtained from the phase 2 study of masitinib in asthma.

This newly issued patent further enhances the Company's key patent family for masitinib, which includes U.S. Patent covering masitinib composition of matter and U.S. Patent covering masitinib synthesis process. These two patents provide exclusivity for masitinib until 2028.

Alain Moussy, CEO and co-founder of AB Science, said: "*This new patent is positive news because it provides an additional four year of exclusivity until 2032 to protect masitinib in severe asthma. This patent is especially welcomed since we intend to launch a new phase 3 with masitinib in patients with severe asthma and elevated eosinophils levels, uncontrolled by high-dose inhaled corticosteroids or oral corticosteroids*".

Previous phase 2 with masitinib in severe asthma uncontrolled by oral corticosteroids

In the phase 2, 44 patients were exposed to masitinib (n=33) or placebo (n=11) for 16 weeks, while being weaned progressively from oral corticosteroids between week 4 and week 16. In the overall population (n=44), the exacerbation rate per month was reduced by 38% between masitinib and placebo (0.23 ± 0.59 with masitinib versus 0.37 ± 0.53 with placebo). In the subgroup of patients uncontrolled with high dose (≥15mg daily) of oral corticosteroids (n=25), the effect was even more profound. The exacerbation rate per month was reduced by 70% between masitinib and placebo (0.19 ± 0.19 with masitinib versus 0.64 ± 0.60 with placebo). This reduction in exacerbation could be achieved while 32% (6/19) of patients could be weaned at the same time from oral corticosteroids in the masitinib group, versus none (0/6) in the placebo group.

On-going phase 3 with masitinib in severe asthma uncontrolled by oral corticosteroids

The current phase 3 study (AB07015) of masitinib in asthma uncontrolled by oral corticosteroid has recently been assessed as non futile by the Independent Data Safety and Monitoring Committee. A futility analysis tests the inability of a clinical study to achieve its efficacy objective, which in the present study is a significant reduction of the frequency of severe asthma exacerbations. The next step is an interim analysis.

Asthma uncontrolled by oral corticosteroid represents the most severe form of asthma (GINA step V patients that are uncontrolled) and represents a high unmet medical need. The quality of life of these patients is severely handicapped, with major reduction in lung function, restrictions on activities of daily living, work absenteeism, nighttime awakening several times a week, frequent exacerbations and greater risk of life-threatening asthma exacerbations. The target population in adult patients is estimated at 70,000 in the USA and in the EU.

New phase 3 in severe asthma with elevated eosinophil level

AB Science intends to initiate a new phase 3 study in severe asthma with elevated eosinophil level. Masitinib is expected to be particularly effective in asthma patients with elevated eosinophils. In a clinical proof of concept study in which asthma was induced in 12 cats using Bermuda grass allergen, masitinib decreased airway eosinophilia and consequently improve pulmonary mechanics. After 4 weeks of treatment, percent eosinophils in Bronchoalveolar lavage fluid (BALF) was lower in masitinib-treated cats (7 ± 9%) versus controls (30 ± 27%, p = 0.023). That represented an absolute decrease of 38.1% of BALF eosinophils in masitinib patients, as compared with an absolute decrease of 12.8% of BALF eosinophils in placebo patients. An improvement in respiratory compliance was also noted with masitinib, as measured by end expiratory occlusion pressure (PEEP) and end inspiratory breath hold pressure (Pplat). The publication can be accessed through the pubmed link: http://www.ncbi.nlm.nih.gov/pubmed/22487554.

About masitinib

Masitinib is a new orally administered tyrosine kinase inhibitor that targets mast cells and macrophages, important cells for immunity, through inhibiting a limited number of kinases. Based on its unique 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. In oncology due to its immunotherapy effect, masitinib can have an effect on survival, alone or in combination with chemotherapy. Through its activity on mast cells and consequently the inhibition of the activation of the inflammatory process, masitinib can have an effect on the symptoms associated with some inflammatory and central nervous system diseases and the degeneration of these 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 class of targeted proteins whose action are key in signaling pathways within cells. Our programs target only diseases with high unmet medical needs, often lethal with short term survival or rare or refractory to previous line of treatment in cancers, inflammatory diseases, and central nervous system diseases, both in humans and animal health.

AB Science has developed a proprietary portfolio of molecules and the Company's lead compound, masitinib, has already been registered for veterinary medicine in Europe and in the USA. The company is currently pursuing 12 indications in phase 3 studies in human medicine, in GIST (in first-line and in second-line), in metastatic melanoma expressing JM mutation of c-Kit, in multiple myeloma, metastatic colorectal cancer, metastatic prostate cancer, pancreatic cancer, mastocytosis, severe persistent asthma, rheumatoid arthritis, Alzheimer's disease, progressive forms of multiple sclerosis, and Amyotrophic Lateral Sclerosis. The company is headquartered in Paris, France, and listed on Euronext Paris (ticker: AB).

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

This document contains prospective information. No guarantee can be given as for the realization of these forecasts, which are subject to those risks described in documents deposited by the Company to the Authority of the financial markets, including trends of the economic conjuncture, the financial markets and the markets on which AB Science is present.

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AB Science – Financial Communication & Media Relations
investors@ab-science.com