Paris, September 22th, 2010 – 7h15 pm

AB Science announces that authorisation has been granted for the initiation of four phase 3 studies in multiple myeloma, rheumatoid arthritis, asthma, and multiple sclerosis.

AB Science SA. (Euronext: AB**)**, announces having received the necessary regulatory approvals to initiate four phase 3 studies with its lead compound masitinib; for which the intent to launch was originally communicated at the time of its initial public offering.

The clinical studies authorised with masitinib are a phase 3 in patients with relapsing multiple myeloma who received one previous therapy, a phase 2b/3 in patients with rheumatoid arthritis, a phase 3 in patients with permanent severe asthma, and a phase 3 in patients with primary progressive or relapse-free secondary progressive multiple sclerosis.

Prior to receiving these authorisations, the design of each study had been validated by one of the major regulatory agencies; the European Medicines Agency (EMA) or the Food and Drug Administration (FDA) in the USA.

Such authorisations are a regulatory prerequisite prior to opening clinical study centres to patient enrolment, which is what the Company will now be focusing on.

Alain Moussy, Chairman and CEO of AB Science commented: *«We are pleased to have achieved these objectives that were set at the time of our initial public offering and to have done so in such short period of time. The authorisations to start these phase 3 studies and the validation of their designs are a significant milestone in the clinical development program of our lead compound masitinib. It is also well worth noting that the medical conditions involved have significant prevalence and account for a high unmet medical need».*

1 - Phase 3 study authorised in multiple myeloma

Characteristics of the study

This study was granted a phase 3 IND (authorisation) by the FDA and its design received a positive scientific advice from EMA.

This is a prospective, multicentre, randomised, double-blind, placebo-controlled, 2-parallel group, phase 3 study to compare efficacy and safety of masitinib 9 mg/kg/day in combination with bortezomib and dexamethazone to placebo in combination with bortezomib (Velcade®) and dexamethazone in the treatment of patients with relapsing multiple myeloma who received one previous therapy.

A total of 300 patients enrolled will be randomised in 2 groups:

- Group 1: 150 patients will receive masitinib in combination with bortezomib and dexamethazone.
- Group 2: 150 patients will receive placebo in combination with bortezomib and dexamethazone.

The primary endpoint is the progression-free survival (PFS) and Overall Survival (OS) will be a secondary endpoint.

Positioning of masitinib in multiple myeloma

The incidence of this cancer is around 50,000 new cases per year in industrialised countries (North America, Northern Europe, Western Europe, Southern Europe, Japan, Republic of Korea, Australia and New Zealand). The indication targeted by masitinib relates to patients in relapse, which represents virtually all patients.

In multiple myeloma, the first line treatment, in young patients, consists of poly-chemotherapy followed by an autologous bone marrow transplant associated with high doses of chemotherapy. Patients who relapse receive more chemotherapy in second line treatment, either Velcade®, which is considered as the standard treatment, or Revlimid®, recently registered. Elderly patients who cannot receive an autologous transplant receive combinations of chemotherapies in first line treatment (melphalan, cyclosphosphamide, corticoids) associated with Thalidomide® or Velcade®.

Masitinib is positioned in second line treatment, but in combination with Velcade®. Consequently, masitinib does not rival Velcade®, but could be in competition with Revlimid®.

There are no other targeted therapies in combination with Velcade® currently in phase 3.

2 - Phase 2b/3 study authorised in rheumatoid arthritis

Characteristics of the study

This phase 2b/3 study was approved by the Afssaps (French health products safety agency) and its design received a positive scientific advice from EMA.

This is a 24-week with possible extension, prospective, multicentre, randomised, double-blind, controlled, 3-parallel groups, phase 2b/3 study to compare efficacy and safety of masitinib at 3 and 6 mg/kg/day to methotrexate, in treatment of patients with active rheumatoid arthritis with inadequate response to i). methotrexate or to ii). any DMARD including at least one biologic drug if patients previously failed methotrexate or to iii). methotrexate in combination with any DMARD including biologic drugs.

A total of 450 patients will be randomised in 3 groups:

- Group 1: patients will receive 3 mg/kg/day masitinib + methotrexate placebo (150 patients)
- Group 2: patients will receive 6 mg/kg/day masitinib + methotrexate placebo (150 patients)
- Group 3: patients will receive masitinib placebo + methotrexate (150 patients)

The primary criterion will be the percentage of responder at week 24, responder being defined as patient with ACR50 at week 24.

Positioning of masitinib in rheumatoid arthritis

Rheumatoid arthritis is a widespread chronic inflammatory disease that affects 0.8% of the population of industrialised countries. It accounts for one of the largest markets for the pharmaceutical industry. The indication targeted by masitinib relates to the treatment of moderate and severe forms of rheumatoid arthritis having failed with methotrexate, which represents around one third of rheumatoid arthritis cases.

The traditional basic treatment starts with anti-inflammatories. The standard treatment line after anti-inflammatories is an inflammation modifier such as chloroquine or salazopirin. In the event of failure, methotrexate, an immunosuppressant not free from long-term toxicity is used. When the patients are resistant to methotrexate, the second line treatment comprises methotrexate in combination with monoclonal antibodies directed against the TNF alpha – anti-TNF alphas. There are several products registered, all in injectable form and which require the daily presence of the patient in hospital or the presence of a nurse. In resistance, the third line comprises methotrexate in combination with a new monoclonal antibody directed against the CD20, a specific antigen of the B cells (CD20), also an injectable treatment.

Masitinib blocks the mast cell, which is one of the immunity cells involved in the immune response and in the inflammation associated with this pathology and the symptoms that arise from it. It has not been ruled out that masitinib also acts in the process for activation of certain immunity cells by the dendritic cells (which express c-Kit). Masitinib therefore represents an oral product different to the products currently on the market, with a mechanism of action that is unique and complementary to the other products by blocking the mast cell.

Masitinib is also set apart by the fact that it can be given alone without methotrexate, thus limiting the long-term toxicity associated with methotrexate.

Masitinib is one of the few tyrosine kinase inhibitors in phase 2b/3 development stage in rheumatoid arthritis. Rigel licensed its compound R788, a Syk inhibitor, to AstraZeneca for the phase 3 development of this drug in rheumatoid arthritis.

3 - Phase 3 study authorised in permanent severe asthma

Characteristics of the study

This phase 2b/3 study was approved by the Afssaps (French health products safety agency) and its design received a positive scientific advice from EMA.

This is a prospective, multicentre, 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.

A total of 300 patients will be randomised in 2 groups:

- Group 1: 200 patients will receive masitinib at 6 mg/kg/day
- Group 2: 100 patients will receive matching placebo

The primary criterion will be the asthma exacerbation rate (severe and moderate exacerbations) at 36 weeks.

Positioning of masitinib in permanent severe asthma

Asthma is a disease which affects 4 to 7% of the population of industrialised countries. The indication targeted by masitinib relates to the treatment of permanent severe asthma, which is around 10% of asthmatic patients.

Masitinib is positioned in the treatment of permanent severe asthma not controlled by inhaled corticosteroid therapy.

Apart from the basic treatments such as corticosteroids and beta-adrenergic receptor inhibitors, only one product is registered in allergic asthma. This is Xolair® from Roche, a monoclonal antibody, injectable product, which however presents the rare but potentially fatal risk of anaphylactic shock.

Masitinib presents a new mechanism of action that aims to block the mast cell, which plays a key role in asthma.

To the Company's knowledge, masitinib is the only protein kinase inhibitor under development in phase 2b/3 in the permanent severe forms of asthma. A phase 3 study is being conducted realised by Pfizer in the same indication to evaluate Tiotropium®, a bronchodilator.

4 - Phase 3 study authorised in multiple sclerosis

Characteristics of the study

This study was granted a phase 3 IND (authorisation) by the FDA and its design received a positive scientific advice from EMA.

This is a 96-week, prospective, multicentre, randomised, double-blind, placebo-controlled, 2-parallel groups, phase 3 study to compare efficacy and safety of masitinib 6 mg/kg/day versus placebo in the treatment of patients with primary progressive multiple sclerosis or relapse-free secondary progressive multiple sclerosis, and with EDSS score of [2.0 to 6.0] inclusive at baseline.

A total of 450 patients will be randomised in 2 groups:

- Group 1: 300 patients will receive masitinib at 6 mg/kg/day
- Group 2: 150 patients will receive matching placebo

The primary criterion will be the proportion of patients presenting with a relative change in MSFC score between baseline and W96 higher (≥) than 100%. With the FDA, a co primary criterion has been added, which is the relative change from baseline to W96 for the two MSQOL-54 summary scores (physical health composite score and mental health composite score)

Positioning of masitinib in multiple sclerosis

Multiple sclerosis is the leading cause of disability in young adults.

Masitinib is positioned in first line treatment of the progressive forms of multiple sclerosis.

There are two forms of multiple sclerosis: the relapse/remission form and the progressive forms. These progressive forms represent around 60% of patients. In the progressive form, there are two sub-forms, which are the secondary progressive form after having begun with the relapse/remission form, and the form that is progressive straight away.

Five products, all administeredd via injection, are registered in the relapse/remission form: three interferons, copaxone and tysabri. No drug is registered in the form of multiple sclerosis that is progressive from the start. In the secondary progressive form no drug is registered in the United States, and only one chemotherapy, mithoxanthrone, which comprises not insignificant risks of secondary cancer, is registered in Europe.

Masitinib is an oral treatment which targets the mast cell, cells which are indirectly involved in multiple sclerosis because:

- they regulate the crossing of the haemato-encephalic barrier;
- the brain is the organ which contains the most mast cells, and the mast cell participates in the recruitment of the T lymphocytes;
- the mast cell can also, via degranulation, contribute to the degradation of the myelin.

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 may 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 is pursuing seven phase 3 studies in human medicine, including three studies on-going in pancreatic cancer, GIST and mastocytosis.

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

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