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AB Science announces recruitment of first patient in phase 3 study of masitinib in multiple myeloma

AB Science now conducting eight phase 3 studies

AB Science SA (NYSE Euronext - FR0010557264 - AB), a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), announced today **recruitment of the first patient in the phase 3 study of masitinib in the treatment of patients with relapsing multiple myeloma who received one previous therapy**. Thanks to the recruitment of the 1st patient in this study, AB Science is now conducting 8 phase 3 studies.

This is an international, multicenter, randomized, double-blind, controlled, phase 3 study. Its objective is to investigate the efficacy and safety of masitinib at 6 mg/kg/day in combination with bortezomib (Velcode®) and dexamethasone as compared with that of a placebo in combination with bortezomib and dexamethasone, in the treatment of patients with relapsing multiple myeloma who have previously received a first line of therapy. This study will enroll approximately 300 patients, across 75 centers around the world, randomized with a ratio of 1:1 between the masitinib/bortezomib/dexamethasone and the placebo/bortezomib/dexamethasone groups. The primary response evaluation will be the Overall Progression Free Survival progression free survival (PFS).

Doctor Bertrand Arnulf (Hôpital Saint Louis - APHP, Paris, France), the principal investigator of this study declared: *"We have shown in preclinical studies that the use of masitinib especially in combination with dexamethasone can exert a synergistic antitumor effect on human multiple myeloma cell lines. Two phase 2 studies have been conducted with masitinib. The first study was conducted in a subset of patients with a poor prognosis due to the presence of a translocation between chromosomes 4 and 14 or t(4; 14). For patients receiving second line treatment with the combination of masitinib and dexamethasone (a corticosteroid) the median survival could be improved by more than 12 months. The second phase 2 study was conducted in patients relapsing within 12 months after first line therapy, with or without t(4; 14), and receiving the combination of masitinib and Velcade® in second line treatment or beyond. This second study has shown good tolerance of masitinib in combination with Velcade® and an improvement for more than 50% of patients when compared to the expected progression free time. These results based on a combination treatment for this disease are encouraging and justify the initiation of this phase 3 study."*

Alain Moussy, President and CEO of AB Science said: "Our objective at the time of the initial public offering was to be conducting eight phase 3 studies within 18 months. We are pleased to report that this objective has been achieved. "

This phase 3 study is fully financed.

About multiple myeloma

Myeloma is the second most common hematological malignancy after lymphomas. It is a cancer of plasma cells, a type of white blood cell normally responsible for the production of antibodies. Localized in the bone marrow, these cells will gradually accumulate and destroy the adjacent bone. As with most other hematological malignancies, the cause of myeloma is not currently known and the disease is not hereditary. The incidence of this cancer is 50 000 new cases per year in industrialized countries (North America, Northern Europe, Western Europe, Southern Europe, Japan, Korea, Australia and New Zealand).

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®. Elderly patients who cannot receive an autologous transplant receive combinations of chemotherapies in first line treatment (melphalan, cyclosphosphamide, corticoids) associated with Thalidomide® or Velcade®.

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 eight studies on-going in pancreatic cancer, GIST, metastatic melanoma expressing JM mutation of c-Kit, multiple myeloma, mastocytosis, severe persistent asthma, rheumatoid arthritis, and progressive multiple sclerosis.

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

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