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AB Science announces recruitment of first patient in phase 2 study in metastatic melanoma

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 2 study evaluating masitinib in metastatic melanoma.

This is a prospective, multicentre, open-label, phase 2 study to evaluate efficacy and safety of masitinib at 9 mg/kg/day in monotherapy and combination with dacarbazine in the treatment of patients with non-resectable or metastatic stage 3 or stage 4 melanoma not carrying a mutation in the juxta membrane of c-kit.

Masitinib is currently evaluated in phase 3 in the 5% of patients with metastatic melanoma carrying a mutation in the juxta membrane of c-kit, with first patients having been enrolled. This proof of concept phase 2 study complements the phase 3 by targeting the remaining 95% of patients with metastatic melanoma. This phase 2 in melanoma will test the monotherapy strategy as in the phase 3 and the combination with chemotherapy strategy. This study is fully financed

Alain Moussy, Chairman and CEO of AB Science declared « This development in melanoma was initiated after observation of positive case reports in dogs suffering from metastatic melanoma and treated with masitinib. After registration of masitinib both in Europe and in the USA in canine mast cell tumours, the veterinary platform creates also value for the development of masitinib in human medicine by delivering information on what indications could be pursued. This type of cross species development is encouraged by NCI guidelines for drugs developable in the two species, which is the case of tyrosine kinase inhibitors since kinases are fairly homologous across mammals ».

Details of the clinical development program (on next page).

About NCI guidelines
The National Cancer Institute's Center for Cancer Research (CCR) has launched the Comparative Oncology Program (COP) to help researchers better understand the biology of cancer and to improve the assessment of novel treatments for humans by treating pet animals-primarily cats and dogs-with naturally occurring cancer.
Further information is available at https://ccrod.cancer.gov/confluence/display/CCRCOPWeb/Home

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 is pursuing nine phase 3 studies in human medicine, including four studies on-going in pancreatic cancer, GIST, in metastatic melanoma expressing JM mutation of c-Kit, and mastocytosis.

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

This document contains prospective information. No guarantee can be given as for the realisation 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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DETAILS OF THE CLINICAL DEVELOPMENT PROGRAM

Scientific rationale for developing masitinib in metastatic melanoma.

Malignant melanoma continues to remain a significant health threat with death often occurring as a result of metastasis. Moreover, metastatic melanoma is a highly chemotherapy resistant tumour.

The use of newer targeted therapies, alone and in combination with chemotherapy may offer new hope of improving treatment in this cancer.

Although it seems obvious to evaluate masitinib in monotherapy in the sub-population of melanoma JM c-kit mutated population (phase 3 on-going), it is also interesting to evaluate the efficacy of masitinib in combination with chemotherapies in the population of melanoma not presenting a JM c-kit mutation. Through its ability to block two kinases, FAK (Focal Adhesive Kinase), and PDGFR, as well as the Wnt/β-catenin Signalling pathway, masitinib combined with chemotherapy, could prevent the development and progression of melanoma lesions, as well as decrease the melanoma resistance to chemotherapy by increasing the drug uptake and therapeutic effectiveness of chemotherapy. Moreover, based on the results obtained in veterinary medicine in dogs with melanoma not presenting a c-kit JM mutation, masitinib in monotherapy might also represent a therapeutic option in human melanomas not presenting c-kit JM mutation.

Focal adhesion kinase (FAK) is a ubiquitously expressed non-receptor tyrosine kinase involved in cancer progression and metastasis. It is found overexpressed in a large number of tumours. FAK regulates integrin and growth factor signalling pathways involved in cell migration, proliferation and survival. These cellular processes, by promoting invasion and metastasis, are implicated in the development and progression of cancer. Studies have shown increased in the constitutive activation of FAK in melanoma cells. In vitro, masitinib (1µM) reduces FAK kinase activity.

PDGFR is a transmembrane receptor tyrosine kinase reported to stimulate angiogenesis and to recruit pericytes. Melanomas widely express PDGFR, and their in vivo resistance to chemotherapy is attributable to high tumour interstitial fluid pressure (IFP). Recent studies have suggested that PDGFR-beta inhibition reduces tumour IFP, and thus increases the uptake of concomitantly administered drugs. In vitro, masitinib is able to inhibit PDGFR kinase activity at submicromolecular ranges (IC50 = 0.49 µM). In cell proliferation assays, masitinib displays an interesting selectivity and inhibits PDGFR-dependent cell proliferation (IC50 = 0.02 µM). These data suggest that masitinib may increase drug uptake and therapeutic effectiveness of chemotherapy for melanoma by inhibiting PDGFR kinase activity.

Wnt/β-catenin Signalling has been shown to be involved in progression, renewal of cancer stem cells and drug resistance of several tumours. This pathway play a role in melanocyte development and could be involved in their transformation in malignant melanoma. Therefore its inhibition could potentially translate in a clinical benefit of patients with melanoma.

Characteristics of the phase 2 study in metastatic melanoma

This is a prospective, multicentre, open-label, two-parallel groups, phase 2 study to evaluate efficacy and safety of masitinib at 9 mg/kg/day in monotherapy and combination with dacarbazine in the treatment of patients with non-resectable or metastatic stage 3 or stage 4 melanoma not carrying a mutation in the juxta membrane of c-kit.

Patients will be randomized in two groups:

- Group 1: patients will receive masitinib in association with dacarbazine
- Group 2: patients will receive masitinib.

The primary criterion will be the Overall Progression Free Survival (PFS), defined as the delay between the date of randomisation to the date of documented progression or any cause of death during the study. Overall Survival will be the main secondary criterion.

Positioning of masitinib in the treatment of melanoma

Melanoma is a malignant tumour that develops from cells called melanocytes, which are present primarily in the skin but are also found in the eye and mucous membranes of the mouth, nose, sinus, rectum and genitals.

The incidence of melanoma has multiplied ten-fold in 50 years. The American Cancer Society estimated there were 68,000 newly diagnosed melanoma cases in the US with 8,700 related deaths in 2009. In France, it is estimated that 7,000 new cases of melanoma are diagnosed each year.

Masitinib is positioned in phase 3 in 5% of the melanoma carrying a mutation in the juxta membrane of c-kit. In this patient population, masitinib is administered in monotherapy at the dose of 7.5 mg/kg/day

Masitinib is also positioned in phase 2 in the other 95% of the melanoma Not carrying a mutation in the juxta membrane of c-kit. In this patient population, masitinib is evaluated in monotherapy and in combination with standard chemotherapy, at the dose of 9 mg/kg/day.