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AB Science announces recruitment of first patient in phase 3 study in metastatic melanoma expressing c-Kit JM mutation

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 3 study comparing masitinib versus dacarbazine in metastatic melanoma bearing the juxtamembrane (JM) mutation of c-Kit.

This is an international, randomised, open-label, phase 3 study to compare the efficacy and safety of masitinib at 7.5 mg/kg/day to dacarbazine in the treatment of patients with non-resectable or metastatic stage 3 or stage 4 melanoma carrying a mutation in the juxtamembrane domain of c-Kit. The trial will enrol approximately 200 patients, across 80 centres around the world, randomised equally between the masitinib and dacarbazine treatment arms.

The mutation of the c-Kit gene is expressed in canine mast cell tumours where masitinib is already registered in Europe and in the USA. This mutation is also present in Gastro Intestinal Stromal Tumours (GIST) where masitinib is currently in a comparative phase 3 study against imatinib.

Alain Moussy, Chairman and CEO of AB Science declared « *There is a race in this indication between Novartis which is starting a phase 3 with nilotinib and AB Science which is already starting a phase 3 with masitinib. Masitinib has been granted authorisation to start phase 3 from FDA without performing a phase 2, leapfrogging competition, mainly due to its results in canine mast cell tumours and GIST. AB Science considers indications where the juxtamembrane mutation of c-Kit is present as priority development for masitinib because these indications hold the highest probability of registration. This phase 3 in melanoma is fully financed* ».

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

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 three studies on-going in pancreatic cancer, GIST and mastocytosis.

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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AB Science is listed on NYSE Euronext Paris (compartiment B) - FR0010557264 - AB
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DETAILS OF THE CLINICAL DEVELOPMENT PROGRAM

Scientific rationale for developing masitinib in metastatic melanoma expressing the JM mutation of c-Kit.

There exists a strong scientific rationale for developing masitinib in the treatment of metastatic melanoma expressing the juxtamembrane (JM) mutation of c-Kit.

1. A large proportion of mucosal melanoma (39%), acro-lentiginous melanoma (36%), and melanoma-induced by sun exposure (28%) express the JM mutation of c-Kit.
2. Clinical data has shown that the single agent administration of imatinib (Glivec), an inhibitor of c-Kit, could induce a prolonged partial tumour response in patients with melanoma expressing the JM mutation of c-Kit.
3. Masitinib is a potent and highly specific inhibitor of c-Kit, and in particular the JM mutation of c-Kit.
 - Masitinib is registered in treatment of canine mast cell tumours with confirmed JM mutation of c-Kit. In this population, it has been shown that subjects receiving masitinib have a statistically significant longer median survival time (241 days versus 83 days).
 - Masitinib is under development in a phase 3 study for treatment of GIST, which is caused by the same JM mutation of the c-Kit receptor. In a phase 2 study for this indication, with over 4 years of patient follow-up, the median survival has not yet been reached and the rate of survival at 4 years was 76%. Median survival without progression was 41.3 months.

Characteristics of the phase 3 study in metastatic melanoma

This is a prospective, multicentre, open-label, active-controlled, two-arm, phase 3 study to compare the efficacy and safety of masitinib at 7.5 mg/kg/day to dacarbazine in the treatment of patients with non-resectable or metastatic stage 3 or stage 4 melanoma carrying a juxtamembrane mutation c-Kit

A total of 200 patients will be randomised in two groups:

Group 1: 100 patients will receive masitinib;

Group 2: 100 patients will receive dacarbazine.

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.

Positioning of masitinib within targeted therapies

Of the new targeted therapies currently under development in the various forms of melanoma:

- For metastatic melanoma expressing the BRAF mutation (i.e. 40% to 60% of melanoma patients), one compound developed by Plexxikon and Roche is currently undergoing phase 3 evaluation.
- For metastatic melanoma expressing the JM mutation of c-Kit (i.e. 5% of melanoma patients), other than masitinib, two other molecules are under development for this indication. Nilotinib (Novartis) has recently initiated a phase 3 study and dasatinib (Bristol-Myers Squibb) is currently in phase 2.

There exist important differences between nilotinib and masitinib beyond their common capacity to inhibit the JM mutation of c-Kit; namely, masitinib also blocks the signalling pathways of WNT/betacatenine and LYN/FAK, two pathways that are important for the proliferation of metastatic melanoma.

Positioning of masitinib within other forms of metastatic melanoma

Chemotherapy is proposed for treatment of metastatic melanoma; however, it does not generate satisfactory clinical results, with a median survival of between just 6 to 12 months (palliative chemotherapy). In metastatic melanoma, a monoclonal antibody developed by Bristol-Myers Squibb, ipilimumab, aimed at stimulating the response of certain cells of the immune system against the melanoma, has been shown to improve median survival by 3.7 months (10.1 months compared to 6.4 months with standard treatment). This product has been filed for registration.

Masitinib is positioned at phase 2 in the treatment of these forms of metastatic melanoma, as monotherapy or in combination with standard chemotherapy.