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AB Science receives authorisation to directly launch a phase 3 clinical study for the treatment of melanoma

The Company currently has nine phase 3 studies in human medicine

AB Science SA (NYSE Euronext - FR0010557264 - AB), a pharmaceutical company specialising in the research, development and commercialisation of protein kinase inhibitors (PKIs), announces having **received regulatory approval to initiate a pivotal phase 3 study for the treatment of metastatic melanoma carrying a mutation in the juxtamembrane (JM) domain of c-Kit.**

Following independent evaluation of the proposed pivotal phase 3 study in melanoma, AB Science received:

- **Positive scientific opinion from the European Medicines Agency (EMA),** including its accord on the study design, which will support a future application for market authorisation of masitinib in the treatment of this type of metastatic melanoma;
- **Investigational New Drug (IND) authorisation from the US Food and Drug Administration (FDA) to conduct this phase 3 study at centres in the USA.**

Exceptionally, AB Science has been authorised to launch this clinical development program directly to phase 3. The major regulatory agencies have judged that results obtained from other masitinib studies conducted by AB Science, provide sufficiently compelling scientific evidence to accelerate the development of this program; namely:

- **Masitinib is already registered for treatment of canine mastocytoma (mast cell tumours) with confirmed mutation of c-Kit**, and is currently commercially available across Europe. 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 gastro-intestinal stromal tumour (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.

Alain Moussy, Chairman and CEO of AB Science declared: ***«****There exists a strong scientific rationale for developing masitinib in melanoma that express the JM mutation of c-Kit. It was essential for us to be able to initiate this program rapidly. For this reason, we are very happy to have obtained authorisation from the FDA to proceed straight to the phase 3 study, without first having to conduct a preliminary phase 2 study, based upon the scientific rationale and clinical data of masitinib in other related cancers (mastocytoma of dogs and GIST in humans)».*

In parallel with this phase 3 study in metastatic melanoma carrying a mutation in the JM domain of c-kit, AB Science has also initiated a phase 2 study in other forms of metastatic melanoma.

AB Science currently has nine phase 3 studies in human medicine, of which eight have received all necessary authorisations to commence recruitment.

This new authorisation is the 8th phase 3 study in human medicine for which AB Science has received the green light to commence.

- **The Company continues development of three phase 3 studies that were in progress before its initial public offering (IPO)** last April, in pancreatic cancer, GIST and mastocytosis.

- **In accordance with objectives communicated at the time of its IPO, it has obtained authorisation for four new phase 3 studies in multiple myeloma, rheumatoid arthritis, asthma, and multiple sclerosis.**

- In addition, **two new major opportunities have been established: one in melanoma, for which phase 3 authorisation has been secured, and the other in Alzheimer's disease.** The latter has already received a positive scientific opinion from the EMA on the design of its proposed pivotal phase 3 study, following highly encouraging results from a related phase 2 study. AB Science now awaits the necessary regulatory authorisations before launching this phase 3 study.

In addition, AB Science continues its advances in veterinary medicine, where its lead compound masitinib is already registered and marketed in Europe (under the name *Masivet®*). **This was a notable landmark, making AB Science the first pharmaceutical laboratory in the world to produce an approved targeted therapy in veterinary oncology;** *Masivet®* having been registered by the EMA in November 2008.

AB Science will present detailed advances in its clinical development program on Friday 8th October 2010 at 8.30 am.
Please contact us if you want to attend this meeting or the conference call (in English) that is scheduled the same day at 11.00 am (Paris time).

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About melanoma
The incidence of melanoma has been rapidly increasing for several years. The incidence of melanoma has increased ten-fold over the past 50 years, and has steadily increased since the 1970s. The American Cancer Society estimated there were 68,000 newly diagnosed melanoma cases in the US with 8,700 related deaths in 2009.

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 eight 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

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 (on the following pages)

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 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 juxta-membrane mutation c-kit

A total of 200 patients will be randomised in 2 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.