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AB Science announces authorization to initiate phase 2 in T-Cell Lymphoma with masitinib

Masitinib clinical development program in haematological malignancies now accounts for 2 indications

AB Science SA (NYSE Euronext - FR0010557264 - AB), a pharmaceutical company specialising in the research, development and commercialization of protein kinase inhibitors (PKIs), announced today the authorisation granted by Afssaps to start a phase 2 clinical study in T-Cell lymphoma with masitinib.

AB Science is now evaluating masitinib in two indications in haematological malignancies, T-Cell lymphoma, in phase 2, and multiple myeloma in phase 3.

As for the phase 2 recently started in human in metastatic melanoma, this development in T-Cell lymphoma was initiated after observation of cases of sustained complete responses reported in dogs suffering from T-Cell lymphoma and treated with masitinib after failure of previous line of treatment.

This phase 2 in T-Cell lymphoma in human will evaluate masitinib in combination with dexamethasone and masitinib in combination with gemcitabine and dexamethasone, in patients with relapsed or refractory peripheral T-cell lymphoma.

Alain Moussy, Chairman and CEO of AB Science declared *«. After registration of masitinib both in Europe and in the USA in canine mast cell tumours, the veterinary platform continues to create 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. This phase 2 is fully financed »*.

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

About peripheral T-Cell Lymphoma
Peripheral T-cell lymphomas (PTCL) represent approximately 15% of all non-hodgkin lymphomas, therefore accounting for around 10.000 new cases per annum in the USA. These lymphomas usually present at diagnosis in stage III or IV, and are often aggressive. There is an important unmet medical need for peripheral T-Cell lymphoma in resistance to one line chemotherapy.

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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AB Science - Financial Communication & Press Relations

Citigate Dewe Rogerson

Contacts Citigate Dewe Rogerson :
Agnès Villeret - Tel: +33 1 53 32 78 95 - agnes.villeret@citigate.fr

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DETAILS OF THE CLINICAL DEVELOPMENT PROGRAM IN HEMATOLOGICAL MALIGNANCIES

Characteristics of the phase 3 in Multiple Myeloma

This is a prospective, multicenter, randomized, 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 and dexamethazone in the treatment of patients with relapsing multiple myeloma who received one previous therapy.

Patients will be randomized into two groups:

- Group 1: Patients will receive masitinib at 9 mg/kg/day in combination with bortezomib and dexamethazone
- Group 2: Patients will receive placebo in combination with bortezomib and dexamethazone

The primary criterion will be the Overall Progression Free Survival (PFS) according to International Myeloma Working Group criteria 2009 (IMWG /revised Bladé criteria).

Characteristics of the phase 2 in T-Cell Lymphoma

A prospective,multicenter, randomised, open-label, three-parallel groups, phase 2 study to evaluate the efficacy and safety of masitinib with dexamethasone, gemcitabine with dexamethasone and the combination of masitinib, gemcitabine and dexamethasone in patients with relapsed or refractory peripheral T-cell lymphoma.

Patients will be randomized in three groups:

- Group 1: Patients will receive masitinib orally at 7.5 mg/kg/day twice daily in combination with dexamethasone
- Group 2: Patients will receive dexamethasone in combination with gemcitabine
- Group 3: Patients will receive masitinib orally at 6 mg/kg/day twice daily in combination with dexamethasone and gemcitabine.

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.