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AB Science announces presentation at ASCO of its 4-year follow-up phase 2 data of masitinib in first line treatment of GIST

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 presentation of its 4-year follow-up data from a phase 2 clinical study of masitinib in the first line treatment of locally advanced or metastatic gastrointestinal stromal tumor (GIST), at the *2011 ASCO Gastrointestinal Cancers Symposium*.

Even though imatinib (Glivec®) has dramatically increased prognosis in this indication, with a median survival time of 55 months and median progression free survival (PFS) of 18 months, according to Blanke et al (JCO 2008), there is still a need for more effective medication in this disease.

The data presented with masitinib are especially important because masitinib is currently being evaluated in a phase 3 head-to-head study with imatinib (Glivec®) in first line treatment. Although the phase 2 study design was a single masitinib arm, it is interesting to compare these results with the published results of imatinib. In particular, the PFS of imatinib in first line treatment is not expected to have changed with time and can therefore be reasonably compared to the PFS of masitinib from this phase 2 study.

PROGRESSION FREE SURVIVAL (PFS)	***Median PFS***	***Rate Year 1***	***Rate Year 2***	***Rate Year 3***	***Rate Year 4***
Masitinib (n=30)	41 months	77%	61%	57%	35%
Imatinib (Publication*)	18 months	≈ 62%	42%	≈ 30%	≈ 25%

SURVIVAL (OS)	***Median OS***	***Rate Year 1***	***Rate Year 2***	***Rate Year 3***	***Rate Year 4***
Masitinib (n=30)	Not reached	97%	90%	87%	75%
Imatinib (Publication*)	55 months	≈ 86%	76%	≈ 61%	≈ 58%

** Blanke et al, JCO 2008*

The abstract to be presented at the *2011 ASCO Gastrointestinal Cancers Symposium* is entitled *« Overall survival benefit with masitinib mesylate in imatinib-naïve locally advanced or metastatic gastro-intestinal stromal tumor (GIST): 4 years follow-up of the French Sarcoma Group phase II trial »* and can be downloaded at :
http://ns207863.ovh.net/~abscienc/file_bdd/1295456962_ascogi2011blayetal.pdf

Masitinib is also being developed for patients resistant to imatinib (Glivec®) in an on-going phase 2 study, which is comparing masitinib to the approved second line drug, sunitinib (Sutent®). Results should be available in 2012. Key variables assessed are overall survival and PFS.

GIST is a disease that is driven by the juxta-membrane mutation of c-Kit, the same genetic mutation on the same gene as that found in canine mast cell tumours, for which masitinib has been registered by EMA and FDA.

Alain Moussy, Chairman and CEO of AB Science declared *« These results are encouraging for mastinib in GIST first line, in particular on PFS with a median of 41 months (versus 18 months for imatinib according to*

the literature). PFS rate at 3 years was 57% for masitinib (compared to just 30% for imatinib) and PFS rate at 4 years was 35% for masitinib (versus 25% for imatinib, according to publication). In the event that this trend is confirmed during phase 3, 200 patients could be enough to demonstrate superiority of masitinib over imatinib. Both the phase 3 in GIST first line and the phase 2 in GIST second line are 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 in the USA 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 IN GIST

Characteristics of the phase 3 in First line treatment of GIST

A prospective, multicenter, randomized, open-label, active-controlled, 2-parallel group, phase III study to compare efficacy and safety of masitinib at 7.5 mg/kg/day to imatinib at 400 or 600 mg in treatment of patients with gastro-intestinal stromal tumour in first line medical treatment

Patients will be randomized into two groups:

- Group 1: Patients will receive masitinib at 7,5 mg/kg/day
- Group 2: Patients will receive receive imatinib at 400 or 600 mg per day

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.

Characteristics of the phase 2 in Second line treatment of GIST

A prospective, multicenter, randomized, open-label, active-controlled, 2-parallel group, phase II study to compare efficacy and safety of masitinib at 12 mg/kg/day to sunitinib at 50 mg/day in treatment of patients with gastro-intestinal stromal tumor resistant to imatinib

Patients will be randomized in two groups:

- Group 1: Patients will receive masitinib at 12 mg/kg/day
- Group 2: Patients will receive sunitinib at 50 mg/day

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.