

# Recruitment of the first patient for the phase 3 study on Gleevec®-resistant GIST, comparing masitinib with sunitinib

Postponement of communication on the results of the phase 3 study of masitinib in pancreatic cancer

Authorization of a new phase 2 study in oncology, in head and neck cancer

**AB Science SA** (Euronext Paris - FR0010557264 - AB), a pharmaceutical company specialized in research, development and commercialization of protein kinase inhibitors (PKI), announces today the recruitment of the first patient in a phase 3 study evaluating masitinib in patients with Gleevec®-resistant gastro-intestinal stromal tumors (GIST) and provides an update on the development program of masitinib in oncology.

### I - Recruitment of the first patient in a phase 3 study in Gleevec®-resistant GIST

This is a phase 3, multicenter, randomized, open-label, controlled, two-parallel group study evaluating the efficacy and safety of masitinib as compared with sunitinib (Sutent®) in GIST patients after progression under imatinib (Gleevec®). This study will recruit around 200 patients from 50 sites around the world, randomized with a 1:1 ratio between masitinib and sunitinib. The primary end-point is overall survival (OS).

This phase 3 study comes after promising results were obtained in a phase 2 study with 44 patients in the same indication, where masitinib has significantly improved overall survival in patients in Gleevec®-resistant GIST when compared with Pfizer's Sutent® (sunitinib), currently the only registered drug for second-line treatment of GIST.

As a reminder, in this phase 2 study, after a median follow-up of 14 months, median overall survival was not reached for masitinib versus 15.2 months for Sutent® (p=0.015 HR: 0.29 [0.10; 0.84]). After 18 months, 79.9% [54.3%; 92.1%] of patients treated with masitinib were still alive, versus 20.2% [1.5%; 54.6%] for patients treated with Sutent®.

Comprehensive and updated results from this phase 2 study will be presented as an oral communication at the 2012 ASCO (American Society of Clinical Oncology) Annual Meeting in Chicago (USA) on June  $4^{th}$ , at 3:00 p.m.

## <u>II – Postponement of communication on the results of the phase 3 study of masitinib in pancreatic cancer</u>

Communication of the phase 3 results of masitinib in pancreatic cancer, previously announced for April 2012 has been postponed.

This postponement is due to the analysis of all study data listed in the protocol taking longer than anticipated, and in particular the genetic data.

AB Science will communicate these results as soon as these data are completely processed.

#### III - Authorization of a new phase 2 study in oncology in Head and Neck cancer

The French Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM) authorized a new clinical phase 2 study in oncology, in head and neck cancer.

The development program for masitinib in oncology currently includes 14 clinical studies – five phase 3 studies, one of which is finished (pancreatic cancer) and nine phase 2 studies.

Clinical Study	Use of masitinib	Status
Phase 3 studies		
1- Pancreatic cancer	Combination with chemotherapy	Data analysis being finalized
2 - GIST First-line	Monotherapy	Recruitment ongoing
3- GIST in resistance to Gleevec <sup>®</sup> (Second-line)	Monotherapy	Recruitment ongoing
4 - Metastatic melanoma with JM mutation of c-Kit	Monotherapy	Recruitment ongoing
5 - Multiple Myeloma in first relapse	Combination with chemotherapy	Recruitment ongoing
Phase 2 studies		
6 - Metastatic melanoma without JM mutation of c-Kit	Combination with chemotherapy	Recruitment ongoing
7 - Metastatic prostate cancer	Combination with chemotherapy	Recruitment ongoing
8 - Metastatic colorectal cancer	Combination with chemotherapy	Recruitment ongoing
9 - Metastatic non small-cell lung cancer	Combination with chemotherapy	Recruitment ongoing
10 - Triple negative breast cancer	Combination with chemotherapy	Recruitment ongoing
11 - Metastatic breast cancer	Combination with chemotherapy	Recruitment ongoing
12 - Metastatic gastric and oesogastric carcinoma	Combination with chemotherapy	Recruitment ongoing
13 - Relapsed or refractory peripheral T-cell lymphoma	Combination with chemotherapy	Recruitment ongoing
14 - Metastatic head and neck cancer	Combination with chemotherapy	Authorization from ANSM

#### About AB Science

Founded in 2001, AB Science is a pharmaceutical company specializing in the research, development and commercialization of novel targeted therapies for patients with cancer or other important diseases with unmet medical needs, including inflammatory diseases and central nervous system diseases.

AB Science has developed its own portfolio of protein kinase inhibitors (PKIs), a new class of targeted molecules, the action of which is to modify signaling pathways within cells. AB Science's lead molecule, masitinib has already been registered in veterinary medicine in Europe and in the USA, and is being tested in ten phase 3 studies in human medicine – including one being analyzed in pancreatic cancer and eight on-going studies: GIST in first-line, GIST in second-line, metastatic melanoma expressing JM mutation of c-Kit, multiple myeloma, mastocytosis, severe persistent asthma, rheumatoid arthritis, and progressive multiple sclerosis. The company is headquartered in Paris and listed on Euronext Paris (ticker: AB).

More information is available on our website: www.ab-science.com.

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