



Paris, 2 December 2013, 6:00 pm

**AB Science announces initiation of a new phase 3 study in oncology with masitinib in patients with metastatic colorectal cancer**

**Phase 3 is designed to confirm the extended survival observed in phase 2, based on masitinib ability to stimulate innate immunity**

**AB Science SA** (NYSE Euronext – FR0010557264 – AB), a pharmaceutical company specialized in research, development and marketing of protein kinase inhibitors (PKIs), announces the initiation of a phase 3 study to evaluate the safety and efficacy of masitinib in combination with FOLFIRI in patients with metastatic colorectal cancer (mCRC) in first relapse.

This is an international, multicenter, randomized, double blind, placebo-controlled, 2-parallel group, phase 3 study to evaluate the efficacy and safety of masitinib in combination with FOLFIRI (irinotecan, 5-fluorouracil and folinic acid) for second-line treatment of patients with metastatic colorectal cancer. The study will measure overall survival as a primary efficacy criterion. One of the objectives of this phase 3 study in colorectal cancer will be to identify those subgroups that best respond to masitinib, similar to the prospective subgroup analyses previously reported in the pancreatic cancer phase 3 study.

The phase 3 study has been authorized by competent authorities.

The decision to move to phase 3 follows encouraging preliminary results from phase 2. Phase 2 has recruited 46 patients and tested three combinations of masitinib with standard-of-care chemotherapies including FOLFIRI, FOLFOX, and gemcitabine. The masitinib plus FOLFIRI combination has proved to be the most efficient and best tolerated one. Median overall survival in the masitinib plus FOLFIRI treatment-arm reached 14.5 months, which compares favorably to published results for FOLFIRI as a single agent at 12.5 months in patients with wild-type KRAS and 11.1 months in patients with mutant KRAS [Peeters et al. 2010].

These data, although preliminary, are important since it is the third time an extended survival has been observed in clinical studies with masitinib as compared to standard-of-care. The first time was in imatinib-resistant GIST, with masitinib generating an additional 12 months median overall survival versus sunitinib. The second time was in first-line treatment of pancreatic cancer, with two subpopulations having poor prognosis (i.e. patients with pain and patients with an aggressive genomic biomarker that flags a poor immune response) respectively reporting an additional median overall survival of 3 and 8 months for masitinib plus gemcitabine with respect to gemcitabine alone. The third time is in metastatic colorectal cancer with the combination masitinib plus FOLFIRI.

Pr. Olivier Hermine, President of the Scientific Committee of AB Science indicated that “those three data converge to show that masitinib’s mechanism of action is capable of generating an important survival benefit in these cancers. AB Science reveals that masitinib in fact targets three cells to stimulate an innate immune response, namely, mast cells, NK cells and macrophages. Unlike other tyrosine kinase inhibitors, masitinib acts also as an immune therapy, the benefit of which is to extend survival by controlling the aggressiveness, transformation, and dissemination of the tumors.”

The incidence of metastatic colorectal cancer is estimated at 370,000<sup>(1)</sup> patients each year in the countries who cover the cost of the treatment.

<sup>(1)</sup> Globocan 2008 – Colorectal Cancer Incidence and Mortality Worldwide in 2008. “Colorectal cancer is the third most common cancer in men (663 000 cases, 10.0% of the total) and the second in women (571 000 cases, 9.4% of the total) worldwide. Almost 60% of the cases occur in developed regions.” [www.snfge.asso.fr](http://www.snfge.asso.fr): « Les métastases sont observées dans 40 à 60% des cas » p.2

### **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 tumor 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 remodeling, 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 specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), a new class of targeted molecules whose action is to modify signaling 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.

AB Science has developed a proprietary portfolio of molecules and the Company's lead compound, masitinib, has already been registered for veterinary medicine in Europe and in the USA, and is pursuing eleven on-going phase 3 studies in human medicine in first-line and second-line GIST, metastatic melanoma expressing JM mutation of c-Kit, multiple myeloma, mastocytosis, metastatic colorectal cancer, severe persistent asthma, rheumatoid arthritis, Alzheimer's disease, progressive forms of multiple sclerosis, Amyotrophic Lateral Sclerosis and in metastatic colorectal cancer. The company is headquartered in Paris, France, and listed on Euronext Paris (ticker: AB).

Further information is available on AB Science website: <http://www.ab-science.com>

*This document contains prospective information. No guarantee can be given as for the realization 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.*

\* \* \*

*AB Science – Financial Communication & Media Relations  
investors@ab-science.com*