



AB Science Announces Clinical Abstracts of phase 1/2 in oncology Accepted at the 2015 European Cancer Congress

AB Science SA (NYSE Euronext - FR0010557264 - AB), a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), today announced that abstracts reporting updated data from three phase 2 studies of masitinib in metastatic colorectal cancer, metastatic esophagogastric adenocarcinoma, and advanced triple negative breast cancer, have been accepted for poster presentation at the upcoming European Cancer Congress 2015 in Vienna (25-29 September 2015). The European CanCer Organisation (ECCO) will release abstracts for general viewing on its website on 11 September 2015.

➤ **Abstracts and schedule**

The list of abstracts and timing of each presentation is provided below, along with brief study summary.

- **Masitinib plus FOLFIRI for second-line treatment of metastatic colorectal cancer: 2-year follow-up of phase 2, open label trial**

Abstract: #2145

Poster: P135

Poster Session: Gastrointestinal Malignancies - Colorectal Cancer (Systemic Therapy)

Date, Location: Sunday, September 27 (9:15 AM - 11:15 AM); Hall C

Professor Julien Taieb of Hôpital Européen Georges Pompidou, Paris, France, principal investigator of this clinical trial, will present updated efficacy and safety data for this prospective, multicenter, open label phase 2 study testing masitinib in combination with chemotherapies including FOLFIRI. AB Science has previously communicated a survival benefit for masitinib plus FOLFIRI (irinotecan, 5-fluorouracil and folinic acid) in this indication with a median OS of approximately 18 months and one confirmed complete response, which compares favorably against historic benchmarks [press release^[1] dated 25 June 2015]. The data to be presented at the upcoming European Cancer Congress will have a median follow-up time in excess of 2 years. The decision to move to the currently recruiting phase 3 study was based on encouraging preliminary results from this phase 2 study, a decision that is corroborated by these follow-up data.

- **Phase 1b/2 study results for masitinib plus irinotecan in second-line treatment of esophagogastric adenocarcinoma**

Abstract: #2349

Poster: P311

Poster Session: Gastrointestinal Malignancies - Noncolorectal Cancer (Systemic Therapy)

Date, Location: Monday, September 28 (9:15 AM - 11:15 AM); Hall C

Professor Aziz Zaanani, of Hôpital Européen Georges Pompidou, Paris, France, a leading investigator on this clinical trial, will present updated efficacy and safety data for this prospective, randomized, open label phase 1b/2 study assessing masitinib in association with chemotherapy for the treatment of recurrent gastric or gastro-esophageal junction adenocarcinoma. Patients received masitinib in combination with irinotecan, or FOLFIRI, or 5-fluorouracil, after progression to platinum-based first-line chemotherapy.

AB Science has previously communicated a survival benefit for masitinib plus irinotecan in this indication with a median OS of approximately 11 months and one confirmed complete response, which compares favorably to numerous published results for second-line irinotecan treatment. Based on the efficacy data

generated from this phase 2 study and the acceptable safety profile of masitinib, AB Science decided to launch a confirmatory phase 3 trial evaluating masitinib at 6 mg/kg/day in combination with irinotecan in second-line [press release ^[1] dated 25 June 2015].

- **Phase 1b/2 study results for masitinib plus gemcitabine and carboplatin in advanced triple negative breast cancer**

Abstract: #1874

Poster: P063

Poster Session: Breast Cancer - Advanced Disease (Systemic Treatment)

Date; Location: Monday, September 28 (9:15 AM - 11:15 AM); Hall C

Professor Mario Campone, of Institut de Cancérologie de l'Ouest, Nantes, France, principal investigator of this clinical trial, will present updated efficacy and safety data for this open-label, randomized, phase 1b/2 study assessing masitinib in association with chemotherapy for the treatment of advanced triple negative breast cancer (TNBC). Patients received masitinib in combination with carboplatin and/or gemcitabine. AB Science has previously communicated a survival benefit for masitinib plus carboplatin and/or gemcitabine in this indication with a median OS of 10.2 months and a response rate of 47%, which compares favorably to published results for carboplatin plus gemcitabine treatment [press release ^[2] dated 12 March 2015]. A decision to continue the development into phase 3 will be taken once results from an on-going phase 2 study in metastatic breast cancer are known. Regarding this latter phase 2 study in metastatic breast cancer, AB Science recently communicated that the external Data and Safety Monitoring Board (DSMB) had recommended study continuation [press release ^[3] dated 02 July 2015], indicating that the benefit-risk balance for masitinib was positive based on data available at that time.

➤ **Comment**

"The abstracts accepted for presentation at this year's European Cancer Congress will provide updated efficacy and safety data for three phase 2 studies from the clinical oncology development program of masitinib" commented Professor Olivier Hermine, President of the Scientific Committee of AB Science. *"The main cellular target of masitinib is the mast cell and increased mast cell activity in the tumor microenvironment has been linked to poor prognosis and a protumoral immune response in numerous cancers. Moreover, unlike other tyrosine kinase inhibitors, masitinib acts also as an immune therapy through its action on macrophages, the benefit of which is to extend overall survival by controlling the aggressiveness, transformation, and dissemination of the tumors. For these reasons masitinib has potential as a novel anticancer agent across a diverse range of oncology indications with digestive cancers (such as colorectal and esophagogastric) and hormonal cancers (such as breast cancer) appearing to be particularly susceptible."*

➤ **References**

(1) AB Science press release dated 25 June 2015, 'Update on phase 1/2 program with masitinib in solid tumors'. Available online at: http://www.ab-science.com/file_bdd/content/1435253923_PressReleasePhase2Onco.pdf

(2) AB Science press release dated 12 March 2015, 'AB Science Reports Positive Phase 2 Clinical Study Data of Masitinib in Triple Negative Breast Cancer'. Available online at: http://www.ab-science.com/file_bdd/content/1426184001_ABSCIENCEPRASCOP2TNBCvENG.pdf

(3) AB Science press release dated 02 July 2015, 'The Data and Safety Monitoring Board recommends continuation of three phase 2 studies assessing masitinib in relapsing liver cancer, breast cancer, and head and neck cancer based on safety and efficacy data'. Available online at: http://www.ab-science.com/file_bdd/content/1435853319_PoursuiteEtudePh2OncoEN.pdf

Status of masitinib clinical development in human medicine

Masitinib is currently developed in 13 phase III indications; 7 in oncology, 3 in inflammatory diseases, and 3 in neurodegenerative diseases. Additionally, a large phase II clinical program is ongoing, mainly in oncology. In case of positive results, phase III studies will be initiated following these phase II studies. Overall, clinical development has been initiated in more than 30 countries, without any licensing agreement. Therefore, AB Science has retained full ownership of masitinib.

About masitinib

Masitinib is a new orally administered tyrosine kinase inhibitor that targets mast cells and macrophages, important cells for immunity, through inhibiting a limited number of kinases. Based on its unique 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. In oncology due to its immunotherapy effect, masitinib can have an effect on survival, alone or in combination with chemotherapy. Through its activity on mast cells and consequently the inhibition of the activation of the inflammatory process, masitinib can have an effect on the symptoms associated with some inflammatory and central nervous system diseases and the degeneration of these 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 class of targeted proteins whose action are key in signaling pathways within cells. Our programs target only diseases with high unmet medical needs, often lethal with short term survival or rare or refractory to previous line of treatment in cancers, inflammatory diseases, and central nervous system diseases, both in humans and animal health.

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. The company is currently pursuing thirteen phase 3 studies in human medicine in first-line and second-line GIST, metastatic melanoma expressing JM mutation of c-Kit, multiple myeloma, metastatic colorectal cancer, metastatic prostate cancer, pancreatic cancer, mastocytosis, severe persistent asthma, rheumatoid arthritis, Alzheimer's disease, progressive forms of multiple sclerosis, and Amyotrophic Lateral Sclerosis. The company is headquartered in Paris, France, and listed on Euronext Paris (ticker: AB).

Further information is available on AB Science website: www.ab-science.com.

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