AB Science announces that three clinical abstracts will be presented at the 2015 ASCO annual meeting

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 the three abstracts reporting on phase 2 studies of masitinib in metastatic colorectal cancer, metastatic esophagogastric adenocarcinoma, and advanced triple negative breast cancer, will be presented at the upcoming 2015 American Society of Clinical Oncology (ASCO) Annual Meeting (May 29 – June 2 in Chicago, Illinois, US).

- **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: An open label phase 1b/2 trial**
    Abstract: #3526
    Poster: #18
    Poster Session: Gastrointestinal (Colorectal) Cancer
    Date, Location: Monday, June 1 (8:00 AM - 11:30 AM); S Hall A

  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 recently communicated that masitinib plus FOLFIRI (irinotecan, 5-fluorouracil and folinic acid) in this indication reached a median OS of approximately 18 months and one confirmed complete response, which compares favorably against historic benchmarks (press release dated 18 December 2014). The decision to move to the currently recruiting phase 3 study was based on encouraging preliminary results from phase 2, a decision that is corroborated by these follow-up data.

  - **Masitinib plus irinotecan for second line treatment of esophagogastric adenocarcinoma: An open label phase 1b/2 trial**
    Abstract: #4027
    Poster: #136
    Poster Session: Gastrointestinal (Noncolorectal) Cancer
    Date, Location: Monday, June 1 (8:00 AM - 11:30 AM); S Hall A

  Professor Aziz Zaanan, of Hôpital Européen Georges Pompidou, Paris, France, a leading investigator on this phase 1b/2 clinical trial, will present the study objectives with updated efficacy and safety data. This was a prospective, multicenter, open-label, randomized, uncontrolled study of 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 recently communicated on preliminary survival data for this indication, which compare favorably to numerous published results for second-line irinotecan treatment (press release dated 02 February 2015). Based on the efficacy data generated from this phase 2 study and the acceptable safety profile of masitinib, AB Science intends to conduct a confirmatory phase 3 trial evaluating masitinib at 6 mg/kg/day in combination with irinotecan in second-line.
Masitinib plus carboplatin and gemcitabine for treatment of patients with advanced triple negative breast cancer: An open label phase 1b/2 trial

Abstract: #1070
Poster: #184
Poster Session: Breast Cancer—Triple-Negative/Cytotoxics/Local Therapy
Date; Location: Saturday, May 30 (8:00 AM - 11:30 AM); S Hall A

Professor Mario Campone, of Institut de Cancérologie de l’Ouest, Nantes, France, principal investigator of this clinical trial, will present the study objectives with updated efficacy and safety data. This was a prospective, multicenter, open-label, randomized, uncontrolled, phase 1b/2 study to evaluate efficacy and safety of 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 recently communicated on preliminary survival data for this indication (press release 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 dated 22 January 2015), indicating that the benefit-risk balance for masitinib was positive based on data available at that time.

Comment

“These studies selected at this year’s ASCO meeting reflect the diverse potential of masitinib as a novel anticancer agent and continued progress in its clinical oncology development program” commented Professor Olivier Hermine, President of the Scientific Committee of AB Science. “The main cellular targets of masitinib are mast cells and macrophages. Tumor-associated macrophages, mast cell and increased mast cell activity in the tumor microenvironment have been linked to poor prognosis and a protumoral immune response in colorectal cancer, gastric cancer and triple negative breast cancer. Unlike other tyrosine kinase inhibitors, masitinib acts also as an immune therapy the benefit of which is to extend overall survival by controlling the aggressiveness, transformation, and dissemination of the tumors.”

References


(2) AB Science press release dated 02 February 2015, ‘AB Science Reports Positive Phase 2 Clinical Study Data of Masitinib in Second-Line Advanced Stomach Cancer’. Available online at http://www.ab-science.com/file_bdd/content/1422897899_ABSCIENCEPRASCOP2gastricv05ENG.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.

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.

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