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AB Science Reports Positive Clinical Study Data

Follow-up of Phase 2 of Masitinib in Second-Line Metastatic Colorectal Cancer confirms Efficacy in Multiple Survival Endpoints

AB Science SA (NYSE Euronext - FR0010557264 - AB), a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), today announced encouraging follow-up results from a phase 2 study with its investigational drug, masitinib, in patients with nonresectable, metastatic colorectal cancer after progression to first-line treatment.

This was a prospective, multicenter, open label phase 2 study testing masitinib in combination with three standard-of-care chemotherapies including FOLFIRI, FOLFOX, and gemcitabine. Primary endpoint was overall survival (OS) and secondary endpoints included progression-free survival (PFS) and overall response rate (ORR). AB Science has previously reported a survival benefit for masitinib plus FOLFIRI (irinotecan, 5-fluorouracil and folinic acid) in this indication based on preliminary data analysis with a median OS of 14.5 months [press release dated 02 December 2013]. One year later, after a median follow-up of approximately 23 months, this survival benefit has been confirmed with a median OS of 18.0 months. Of note, approximately 50% of the masitinib plus FOLFIRI treatment cohort were positive for the *KRAS* mutation. These results compare favorably to published results for second-line FOLFIRI treatment in which median OS was reported as 12.5 months in patients with wild-type *KRAS* and 11.1 months in patients with mutant *KRAS* [Peeters et al. (2010) J Clin Oncol 28: 4706–4713].

The survival endpoints of PFS and ORR were also favorable for masitinib plus FOLFIRI when compared with historic benchmarks, regardless of *KRAS* mutation status. In the overall study population, median PFS was 6.2 months as compared with 3.9 to 4.9 months for the FOLFIRI benchmark, and ORR was 28% as compared with 10% to 14% for the FOLFIRI benchmark [Peeters et al. (2010) J Clin Oncol 28: 4706–4713]. Of significance, one patient reported a confirmed complete response, which is an exceptional observation in this clinical setting. Safety data showed that the combination of masitinib and FOLFIRI has an acceptable safety profile. Full data has been submitted for publication to the American Society of Clinical Oncology (ASCO) 2015 Annual Meeting.

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.

Professor Christophe Borg (University Hospital, Besançon, France), and a leading investigator on this study declared: "R*esults from this phase 2 study are impressive. Of particular interest is the comparatively high overall response rate. In comparison the current effect of FOLFIRI alone or in combination with bevacizumab is very limited regarding response rate. These data, although preliminary in nature, suggest that masitinib may potentially offer patients a new active compound for this disease. Results from the ongoing comparative phase 3 study will therefore be of great interest.*"

Professor Olivier Hermine, President of the Scientific Committee of AB Science commented: "*The survival benefit seen across OS and PFS is consistent with our understanding of masitinib's mechanisms of action in colorectal cancer. In vitro data on colorectal cell lines has shown that masitinib acts as a chemosensitizer of 5-Fluorouracil and irinotecan, the two main cytotoxic components of FOLFIRI, which may explain improvement in PFS. Also, 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 colorectal cancer. Moreover, 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. Together, these mechanisms of action represent a strong biological rationale for masitinib in this indication."

A significant unmet medical need still exists in metastatic colorectal cancer. The incidence of metastatic colorectal cancer is estimated at 370,000[(1)] patients each year in the countries who cover the cost of the treatment.

(1) 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: « Les métastases sont observées dans 40 à 60% des cas » p.2

Characteristics of the ongoing phase 3 study in metastatic colorectal cancer

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. A total of 550 patients enrolled will be randomised in two groups:

- Group 1: masitinib at 6 mg/kg/day + FOLFIRI (irinotecan, 5-fluorouracil and folinic acid), until disease progression
- Group 2: matching placebo + FOLFIRI (irinotecan, 5-fluorouracil and folinic acid), until disease progression

The study will measure overall survival as a primary efficacy criterion. One of the objectives of this ongoing phase 3 study in colorectal cancer will be to identify those subgroups that best respond to masitinib.

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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