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AB Science Reports Positive Phase 2 Clinical Study Data of Masitinib in Triple Negative Breast Cancer

Data submitted for publication to the American Society of Clinical Oncology (ASCO) 2015 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 positive efficacy and safety results from a phase 2 study with masitinib in patients with triple negative breast cancer (TNBC).

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 TNBC. Patients received masitinib in combination with carboplatin and/or gemcitabine.

In the cohort receiving masitinib in combination with carboplatin and gemcitabine, 37% of patients enrolled were in first-line of treatment, 16% were in second-line of treatment and 47% were in third-line of treatment or beyond. For the overall cohort, median overall survival was 10.2 months and median progression-free survival was 4.7 months. Objective response rate was 43%.

The efficacy of masitinib in combination with carboplatin and gemcitabine compares favorably to median OS of 7.7 months and response rate of 32% published for carboplatin plus gemcitabine in the treatment of TNBC[1].

A statistical test was pre-defined in this phase 2 study in order to detect a superiority trend on the overall survival between the median value of the study and historical median value. The result of this test enables to determine whether or not a confirmatory phase III could be initiated. This statistical test is based on the upper bound for the confidence interval of Hazard Ratio lower than 1, estimated from the median Overall Survival (OS) observed in this phase 2 study and the historical benchmark. In the masitinib + gemcitabine + carboplatin group, upper bound of the confidence interval for OS hazard ratio is estimated to 0.70, permitting to justify the launch of a larger study. AB Science is currently discussing with the experts of the disease the next steps of clinical development.

Full safety and efficacy data has been submitted for publication to the American Society of Clinical Oncology (ASCO) 2015 Annual Meeting.

"The phase 2 efficacy results of masitinib in combination with carboplatin and gemcitabine for the treatment of advanced triple negative breast cancer are quite encouraging," said Professor Mario Campone of the Institut de Cancérologie de l'Ouest, Nantes, France, and the principal investigator of this study. *"A significant unmet medical need still exists for treatment of advanced triple negative breast cancer, and the development of targeted agents such as masitinib in combination with cytotoxic drugs has potential to improve patient survival in this disease."*

TNBC is more aggressive than other forms of breast cancer, with fewer treatment options and no drug registered in this specific indication. The benchmark for median overall survival in metastatic breast cancer is estimated at 18 months[2] in second-line of treatment, TNBC not included, whereas it is less than 7.7 months in second-line treatment of TNBC. Hence, there is still a high unmet medical need in this disease.

Breast cancer remains the second most common cancer in the world, and kills more women than any other cancer type. The incidence of breast cancer is reported as approximately 600,000 patients in the USA and Europe, and the mortality rate was of 130,000 patients[3]. It is estimated that 15% of patients have TNBC.

It is also estimated that up to 40% of those diagnosed with breast cancer will develop advanced disease within 10 years.

With these hypotheses, the number of eligible patients for treatment of advanced triple negative breast cancer is estimated to be 36,000 per annum in Europe and USA.

[1] Shaughnessy. N Engl J Med 2011;364:205-14. / Note :The referenced study enrolled 60% of patients in first-line, and 40% in second-line or beyond.

[2] References from meta-analysis

[1] Kaufmann M et al, Eur J Cancer, 2010 Dec; 46(18):3184-91
[2] Barrios CH et al, Breast Cancer Res Treat. 2010 May;121(1):121-31
[3] Sparano J et al, J Clin Oncol. 2010 Jul 10;28(20):3256-63
[4]Stockler M et al, J Clin Oncol. 2011 Dec 1;29(34):4498-504
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[6]Baselga J et al, J Clin Oncol. 2012 May 1;30(13)
[7]Blum LJ et al, Breast Cancer Res Treat. 2012 Dec;136(3):777-88
[8]Park Y et al, Journal of tumor, 2014 April 18 2(4):113-121

[3] http://eco.iarc.fr/eucan/ ; http://seer.cancer.gov/statfacts/html/breast.html

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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