Paris, 15 July 2015, 6:00 pm

AB Science announces initiation of an adaptive design phase 2/3 study with masitinib in patients with refractory metastatic ovarian cancer

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 seamless adaptive design phase 2/3 study to evaluate the safety and efficacy of masitinib in combination with gemcitabine in patients with refractory advanced or metastatic epithelial ovarian cancer.

This is an international, multicenter, open-label, centrally allocated, active-controlled, phase 2/3 study to evaluate the efficacy and safety of masitinib in combination with gemcitabine as compared with single-agent gemcitabine in advanced or metastatic epithelial ovarian cancer patients who are refractory to first-line platinum treatment or are in third-line. The study's primary efficacy measure will be overall survival.

Adaptive design

In recent years it has become evident that a more flexible methodology can substantially increase the chance to demonstrate the superiority of a novel treatment, reducing the time needed for new drug development.

An adaptive design clinical study is a study that includes a prospectively planned opportunity for modification of one or more specified aspects of the study design and hypotheses based on analysis of data (usually interim data) from subjects in the study.

Such phase 2/3 adaptive trials are confirmatory in nature. The first stage of a seamless adaptive phase 2/3 trial might be similar to a late phase 2 trial with a control group and different treatment groups (for example, subgroup analyses). Results are examined at the end of the first stage, and one or more of the treatment groups are selected to continue, along with the control group in the trial's second stage. The final analysis comparing the selected groups with the control will use data from the continuing groups from both stages of the trial.

Compared to performing a phase 2 study followed by a separate confirmatory phase 3 study, an adaptive design allows a Sponsor to potentially accelerate time to registration by:

- shortening the clinical development program via elimination of time lag between phase 2 and phase 3 trials
- allowing greater efficiency in the use of data from both stages, which might mean that fewer patients are required to obtain the same quality of information; and
- enabling the earlier acquisition of long-term safety data, gathered through continued follow-up of patients from the first stage.

Compared to transforming a phase 2 study directly into a phase 3 study, as was done with masitinib in amyotrophic lateral sclerosis or more recently in T-cell lymphoma, the adaptive design allows a Sponsor to:

- in the case the drug is effective, move to phase 3 with greater certainty and efficiency, thereby increasing the chance of success, or
- in the case the drug in not effective, reduce the number of patients and limit the financial investment.

The adaptive design makes the study more efficient (e.g., shorter duration, fewer patients), and more likely to demonstrate an effect of the drug, if one exists.

The design of the study in ovarian cancer is a two-stage adaptive design, which allows AB Science to modify two parameters.

- The study population:
  This is important because heterogeneity in ovarian tumor biology necessitates subgroup analyses to better identify those patients most likely to benefit from masitinib. The populations to be tested include: the overall population; the subpopulation with pain at baseline, which is expected to be a marker of mast cell related tumor progression; and the subpopulation with overexpression of ACOX-1, which is expected to be a marker of macrophage mediated pro-tumoral immune response. Masitinib is expected to be more effective in these two subpopulations given its mechanisms of action.
  The adaptive component of the study will reveal if recruitment should be continued in the overall population, or in one or both of the subpopulations, or if the study should be terminated early.

- The sample size:
  In case the study continues into phase 3, the adaptive component of its design will tell if the study should be resampled based on the magnitude of the efficacy observed.

Alain Moussy, co-founder and CEO of AB Science commented: *"AB Science has developed internally the capabilities to implement adaptive designs, which is a new asset in clinical development."*

Status of the study

The phase 2/3 study has been authorized by competent authorities, and the first patients have been enrolled.

The incidence of metastatic ovarian cancer

Ovarian cancer remains the fifth leading cause of cancer death in women. The incidence of ovarian cancer is reported as approximately 65,000 patients in the USA and Europe, and the mortality rate was of 44,000 patients[1]. The most common type of ovarian cancer is called ovarian epithelial cancer.

Approximately 85% of ovarian cancer patients are diagnosed with advanced stage of the disease. It is estimated that 60% of patients progressing after first-line treatment of cancer can receive a second-line of treatment.

With these hypotheses, the number of eligible patients with refractory advanced or metastatic epithelial ovarian cancer is estimated to be 33,000 per annum in Europe and USA.

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.

[1] http://eco.iarc.fr/eucan/CancerOne.aspx?Cancer=27&Gender=2 ; http://seer.cancer.gov/statfacts/html/ovary.html

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.

* * *

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