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Phase 2 with masitinib in peripheral T-cell lymphoma accelerated into phase 3

Acceleration into phase 3 authorized by Health Autority in 14 countries

First patient of phase 3 stage recruited

AB Science SA (NYSE Euronext – FR0010557264 – AB), a pharmaceutical company specialized in research, development and marketing of protein kinase inhibitors (PKIs), announces that its phase 2 with masitinib in relapsed or refractory peripheral T-cell lymphoma (PTCL) was accelerated into a phase 3 randomized controlled trial.

This phase 2-3 study is a prospective, multicenter, open-label, three-parallel groups, randomized trial to evaluate the efficacy and safety of masitinib plus dexamethasone with or without gemcitabine, as compared against the active control of dexamethasone plus gemcitabine, in patients with relapsed or refractory peripheral T-cell lymphoma. The primary endpoint of this study is overall survival.

The clinical development program of masitinib in peripheral T-cell lymphoma started with a phase 2, open-label, three-parallel groups, randomized study, which involved the planned recruitment of 45 patients. Health authorities from 14 countries agreed to transform the phase 2 study directly into phase 3, with prospective recruitment of 270 patients.

The decision to accelerate the phase 2 into phase 3 was based on the observation of a survival benefit with masitinib as compared to control (data blinded to sponsor and investigator) and acceptable safety with validation of the passage into phase 3 by the independent Data Monitoring Safety Board.

Alain Moussy, CEO and co-founder of AB Science commented: "*We decided to accelerate the development of masitinib in PTCL because, as for amyotrophic lateral sclerosis (ALS), PTCL is a rare disease with a high unmet medical need, there is a strong biological rationale to develop masitinib this indication and there was no safety concern. The authorization of this acceleration in phase 3 by multiple agencies in the world confirms this analysis. Moreover and unlike in ALS, the transformation from phase 2 to phase 3 status is supported by encouraging clinical data in dogs where cases of complete responses have been reported with masitinib single agent.*"

Previous case reports and publications from veterinary medicine

Dogs also suffer from T-cell lymphoma. The advantage to look at cases from veterinary medicine is that these cases are not models but reflect natural disease as in humans. Since masitinib is registered in veterinary medicine, the observation of canine cases is relevant.

Response to treatment of canine T-cell-multicentric lymphoma is classically described as poor, especially for pleomorphic and lymphoblastic forms, with median survival times of less than 8 months in most studies focusing on the interest of conventional chemotherapy.

Two promising cases were reported in dogs with T-cell lymphoma treated with masitinib. Two female dogs were presented for T-cell lymphoma. Both dogs had been previously treated with glucocorticoids. The first

dog also initially received vincristin (as part of a CHOP based protocol), but treatment was poorly tolerated. The second dog received one initial administration of L-asparaginase. Both dogs then received masitinib after this initial period. In the 2 dogs, masitinib was well tolerated. Progressive complete remission was reached in the first dog. The animal was still alive with complete remission and a good tolerance of masitinib for maintenance after more than 16 months of follow-up. Rapid complete remission was reached in the second dog. The animal was still alive with complete remission and a good tolerance of masitinib for maintenance after more than 8 months of follow-up.

A recent veterinary study with 11 dogs reported impressive signs of masitinib treatment-effect in canine T-cell lymphoma, with dogs receiving monotherapy masitinib showing an Objective Response Rate of 72%, including 3 dogs with complete repose and 5 dogs with partial response over a sustained period. In other examples, masitinib monotherapy was sufficient to maintain a complete or clinical remission when administered as maintenance chemotherapy to dogs with T-cell lymphoma. Overall, these and other similar case reports provide compelling support for the development of masitinib in human peripheral T-cell lymphoma.

These observations are consistent with a recent publication on canine lymphoma, concluding that the use of PDGFR inhibitor in the therapy of aggressive T-cell lymphomas represents a viable treatment strategy. The publication can be accessed through the PubMed link: http://www.ncbi.nlm.nih.gov/pubmed/25172054.

Scientific rationale

Peripheral T-cell lymphomas not otherwise specified (PTCL/NOS) and other aggressive forms of T-cell lymphomas are fast growing tumors characterized by consistent aberrant expression of platelet-derived growth factor receptor alpha (PDGFRA). A recent publication demonstrated that PDGFRA activity fosters PTCL/NOS proliferation via an autocrine loop. This publication can be accessed through the PubMed link: http://www.ncbi.nlm.nih.gov/pubmed/24480986.

Masitinib is an orally administered tyrosine kinase inhibitor that targets a limited number of kinases that play key roles in various cancers. Masitinib has two potential mechanisms of action effective in T cell Lymphoma. First, masitinib is a potent inhibitor of platelet-derived growth factor receptor, an important target in T cell Lymphoma. Second, pre-clinical data and cumulative clinical experience show that masitinib also acts as an immune therapy trough targeting the innate immune system through mast cells and marcophages, the benefit of which is to extend survival by controlling the aggressiveness, transformation, and dissemination of the tumors.

Professor Olivier Hermine, President of the scientific committee of AB Science and head of hematology department at Paris Necker Hospital explained: "*PTLC remains a challenging disease. The oncogenic factors in PTCL are not yet fully elucidated. However, among these factors, it has been shown that in around 80% of cases, the receptor to PDGF kinase is abnormally increased in the lymphoma T-cells. The receptor can be activated by its natural ligand, PDGF, and trigger a proliferation of T cells that are resistant to chemotherapy. We therefore hypothesized that inhibiting the PDGF receptor in refractory PTCL could increase the survival of patients. Masitinib is a potent inhibitor of the PDGF receptor. Since we already know that masitinib can increase survival through the control of both mast cells and macrophages, masitinib becomes a strong candidate drug in refractory T cell lymphoma with two good reasons to expect increased survival".*

About refractory T-cell lymphoma

Peripheral T-cell lymphomas (PTCL) represent approximately 15% of all non-Hodgkin lymphomas, therefore accounting for around 25,000 new cases per annum in the USA and in the EU. These lymphomas are usually present at diagnosis in stage III or IV, and are often aggressive. There is an important unmet medical need for peripheral T-Cell lymphoma in resistance to one line chemotherapy.

Patients with relapsed or refractory T-cell lymphoma have a poor prognosis with a median overall survival of around 6 months and a progression free survival around 3 months. No drug is approved in this population in Europe and patients are treated using conventional chemotherapy as gemcitabine.

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 12 indications in phase 3 studies in human medicine, in GIST (in first-line and in second-line), in metastatic melanoma expressing JM mutation of c-Kit, in 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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