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Masitinib in Amyotrophic Lateral Sclerosis (ALS) – Summary of Web Conference

Ongoing phase 3 study in ALS successfully passes futility test

IDMC recommends continuation of phase 3 study based on review of safety and efficacy data

Interim analysis is planned for Q1 2016

AB Science SA (NYSE Euronext – FR0010557264 – AB), a pharmaceutical company specialized in research, development and marketing of protein kinase inhibitors (PKIs), provides a summary of the key points of the web conference held on 11 May 2015 with key opinion leaders on masitinib in the treatment of amyotrophic lateral sclerosis.

Amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease and Charcot disease, is a life-threatening neurological disease that causes muscle weakness, disability and eventually death. Only around 10% of patients live past 10 years with 80% of patients die within 5 years. ALS represents a high unmet medical need with an estimated combined target population in the USA and EU of 50,000 patients.

A growing body of evidence suggests that ALS is a neurodegenerative disorder in which cross-talk between microglia, mast cells and astrocytes may destroy motor neuron. Masitinib targets both mast cells and microglia and was shown to be capable of reducing death and atrophy of motoneurons in mice and rat models, thereby establishing the mechanistic mode of action for masitinib in ALS.

In the ALS mice model ($SOD1^{G93A}$), masitinib was able to delay disease onset and to reduce loss of muscle strength. In the ALS rat model ($SOD1^{G93A}$), masitinib was able to significantly increase survival, even when masitinib was administered 7 days after the onset of paralysis, a data that is unparalleled in the scientific literature to date.

A phase 3 study (AB10015) that plans to recruit 380 patients is ongoing. The study objective is to compare the efficacy and safety of masitinib plus riluzole with placebo plus riluzole. The primary end point is to measure the change in ALSFRS-R at week 48. The ALSFRS-R score is a validated rating instrument for monitoring the progression of disability in patients with ALS, which correlates significantly with quality of life and survival. This endpoint is recommended by EMA and FDA guidelines for registration in ALS.

An Independent Data Safety and Monitoring Committee (IDMC) reviewed data of the study in an unblinded manner.

The IDMC has reviewed the study's safety data twice, the last review being performed in December 2014, and recommended continuation of the study on each occasion, indicating that there are no safety issues associated with this study.

The IDMC recently assessed study efficacy based on a futility test with one third of the patients enrolled and having reached the 48-week time point. This futility test was based on the same hypothesis as the final hypothesis but projected the trend observed from patients recruited thus far and takes into account the standard deviation observed. IDMC reported that study AB10015 is non futile. This futility test was supported by four sensitivity analyses provided to the IDMC to ensure robustness of the test.

The next step is an interim analysis that has been pre-specified in the protocol. This interim analysis includes a pre-planned resampling option with a maximum of times two (i.e. the possibility to enroll up to twice the initial number of patients), should the trend observed at the interim analysis be insufficient for the study to be successful with the initial number of patients planned.

Consequently, there are four possible outcomes for the interim analysis:

a. Interim analysis is a success. Depending on discussion with agencies and ethical committees there is a possibility that study could be stopped and a registration dossier filed.
b. Interim analysis fails but study continues without re-sampling. This implies that the study is expected to be a success following recruitment of the 50% remaining patients, based on projected trends.
c. Interim analysis fails but study continues with re-sampling. This means that by increasing the sample size by a maximum factor of 2 the study is expected to be a success.
d. Interim analysis fails and study stops. This means that even by doubling the sample size, the study is expected to fail. This scenario, which corresponds to stating that the study is futile, is however less likely to occur since the study has successfully passed the futility test with one third of the patients enrolled.

Timing of the interim analysis is planned for Q1 2016 and is certain since the recruitment of 50% of patients necessary for this interim analysis has already been reached. Depending on speed of recruitment, final analysis without resampling could be reached in Q4 2016.

Intellectual property for masitinib is secured for the use of ALS until 2028 through composition of matter and synthesis patents, which have been issued worldwide. An additional method of use patent that is currently under prosecution may potentially protect the use of masitinib in ALS until 2034.

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 lines of treatment in cancers, inflammatory diseases, and central nervous system diseases, both in human 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's website: www.ab-science.com

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