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AB Science announces that Rapporteurs appointed by the EMA, after reviewing interim data, have recommended the filing of masitinib in amyotrophic lateral sclerosis (ALS) for conditional marketing authorization

Filing at EMA for conditional marketing authorization is expected by Q3 2016

AB Science SA (NYSE Euronext – FR0010557264 – AB), a pharmaceutical company specialized in the research, development and marketing of protein kinase inhibitors (PKIs), announced today that Rapporteurs appointed by the European Medicines Agency (EMA) have recommended the filing of masitinib in combination with riluzole in the treatment of adult patients with amyotrophic lateral sclerosis (ALS) for conditional marketing authorization.

This request for filing was based on clinical data from the phase 2/3 study AB10015, which was successful on its pre-specified primary endpoint at the interim analysis, as well as preclinical data on masitinib mechanism of action in ALS, and manufacturing process.

Three pre-submission meetings were held in May 2016, one with the Rapporteur and his team, one with the co-Rapporteur and his team, and one with the EMA coordinator, to assess the request for filing of masitinib in combination with riluzole in the treatment of adult patients with ALS.

The following points were reviewed during these pre-submission meetings:

- Compliance of the study design with the EMA guidance on clinical trials in ALS
- Clinical relevance of the treatment effect based on the study's primary endpoint data, in particular the change in slope of decline in ALSFRS between masitinib and placebo
- Significance of the study results :
 - o the p-value of the primary analysis
 - o the consistency of sensitivity analyses on the primary analysis
 - o the convergence of treatment effects on secondary analyses, including quality-of-life which is an important endpoint for EMA
- The absence of bias due to center effect or baseline characteristics
- The safety profile based on frequency of serious adverse events, and advent events leading to treatment discontinuation
- Plausibility of the mechanism of action of masitinib in ALS
- Timing of availability of final data from study AB10015
- The resolution of objections concerning the manufacturing raised by EMA during the previous evaluation in GIST

Based on the review of these points, the Rapporteurs have recommended AB Science to submit its application for conditional marketing authorization for masitinib in combination with riluzole in the treatment of adult patients with amyotrophic lateral sclerosis.

AB Science expects to file this application for conditional marketing authorization by the end of Q3 2016.

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 microglia 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 twelve 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, T-cell lymphoma, severe asthma uncontrolled by oral corticosteroid, 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: <http://www.ab-science.com>

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