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AB Science announces positive top-line results of final analysis from study AB10015 of masitinib in amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease

Primary analysis is a success and confirms interim analysis

Company to host webcast on masitinib in ALS

AB Science SA (NYSE Euronext - FR0010557264 - AB), a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), today announced that the phase 2/3 study AB10015 of masitinib in amyotrophic lateral sclerosis (ALS) has met its pre-specified primary endpoint. This is the first successful phase 3 trial of a tyrosine kinase inhibitor in the treatment of ALS, signifying masitinib as first-in-class for ALS, with a unique mechanism of action against microglia cells.

A webcast will be hosted on 20 March 2017 at 6 pm (CET). To participate please email at linda.carlet@ab-science.com.

Study AB10015 was a double-blind, placebo-controlled phase 2/3 study to compare the efficacy and safety of masitinib in combination with riluzole, versus placebo in combination with riluzole in the treatment of patients suffering from ALS.

In accordance with study protocol, the final analysis was performed based on 394 patients treated for 48-weeks and randomly allocated to three different treatment arms: masitinib at 4.5 mg/kg/day, versus masitinib at 3 mg/kg/day, versus placebo, each administered as an add-on to riluzole. The primary endpoint was based on the change from baseline to week 48 in the revised Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS-R). 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. Also consistent with EMA guidance, Progression Free Survival (PFS) was included as a key secondary endpoint for registration, with progression being defined as ALSFRS-R deterioration of more than 9 points or death. A stepwise sequence of analysis was predefined to first test masitinib at 4.5 mg/kg/day versus placebo, and then masitinib at 3 mg/kg/day versus placebo.

For masitinib at 4.5 mg/kg/day:

- Primary analysis on the change in ALSFRS-R score at week 48 (mLOCF methodology) is statistically significant with a P-value of 0.014.
- Sensitivity tests on the primary analysis consisted in two models to impute a value at week 48 for any patients who discontinued treatment before week 48. Those sensitivity analyses are also significant with a P-value of 0.020.
- The key secondary analysis on PFS was statistically significant with a P-value of 0.016.
- Quality-of-life measured by change in ALSAQ score was also statistically significant with a P-value<0.01.

For masitinib at 3 mg/kg/day:

- There was a trend in favor of masitinib versus placebo for change in ALSFRS score at week 48 (LOCF methodology) and likewise for the two imputation models (sensitivity analyses) and in PFS (secondary analysis).
- The change in quality-of-life was statistically significant (p-value<0.01) in favor of masitinib.

The adverse events observed for masitinib in study AB10015 were consistent with its known safety profile. There were no new safety events at final analysis as compared with interim analysis.

The final analysis confirms the interim analysis, which was performed with 50% of patients.

AB Science filed an application for marketing authorization of masitinib in ALS at EMA in September 2016. Full efficacy and safety data will be submitted for presentation at the European Network for the Cure of ALS (ENCALS) annual meeting in Ljubljana, Slovenia (18 – 20 May, 2017).

Alain Moussy, CEO of AB Science said: "*This is a very good news for the patients. These final data confirm findings from the study's interim analysis and proves that masitinib is capable of slowing down motoneuron degenerative disease such as ALS, which is a devastating condition with an urgent unmet medical need.*"

Professor Olivier Hermine, President of AB Science scientific committee declared: "*Perhaps the most impressive finding from this study is that masitinib has generated a significant difference in progression free survival with respect to the placebo treatment-arm. Similar to cancer studies when PFS is significantly improved, this indicates a clear clinical benefit in favor of masitinib.*"

Dr. Jesús Mora Pardina, international coordinator of study AB10015 and neurologist expert in ALS declared: "*Masitinib is one of the rare drugs developed for the treatment of ALS that has proved its efficacy through validated endpoints. These results are truly encouraging and can be considered as a major breakthrough for ALS treatment, a condition that has proved extremely challenging in the development of new effective medication. Masitinib may be the long-awaited addition to the therapeutic armamentarium of ALS."*

The mechanism of action of masitinib in ALS is based on the targeting of neurotoxic aberrant glial cells via CSF1R inhibition, providing a neuroprotective effect and slowing down neurodegeneration.

Amyotrophic lateral sclerosis is a rare degenerative disorder that results in progressive wasting and paralysis of voluntary muscles. There are approximately 50,000 people with ALS in the European Union and in the US, with more than 16,000 new cases diagnosed each year in Europe and in the US. Almost 80% of ALS patients die within 5 years and 90% die within 10 years.

Masitinib received orphan drug designation for ALS from both EMA and FDA.

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 thirteen phase 3 studies in human medicine in metastatic prostate cancer, metastatic pancreatic cancer, relapsing metastatic colorectal cancer, relapsing metastatic ovarian cancer, GIST, metastatic melanoma expressing JM mutation of c-Kit, relapsing multiple myeloma, relapsing T-cell lymphoma, mastocytosis, severe asthma, amyotrophic lateral sclerosis, Alzheimer's disease and progressive forms of multiple 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.

Forward-looking Statements - AB Science
This press release contains forward-looking statements. These statements are not historical facts. These statements include projections and estimates as well as the assumptions on which they are based, statements based on projects, objectives, intentions and expectations regarding financial results, events, operations, future services, product development and their potential or future performance.

These forward-looking statements can often be identified by the words "expect", "anticipate", "believe", "intend", "estimate" or "plan" as well as other similar terms. While AB Science believes these forward-looking statements are reasonable, investors are cautioned that these forward-looking statements are subject to numerous risks and uncertainties that are difficult to predict and generally beyond the control of AB Science and which may imply that results and actual events significantly differ from those expressed, induced or anticipated in the forward-looking information and statements. These risks and uncertainties include the uncertainties related to product development of the Company which may not be successful or to the marketing authorizations granted by competent authorities or, more generally, any factors that may affect marketing capacity of the products developed by AB Science, as well as those developed or identified in the public documents filed by AB Science with the Autorité des Marchés Financiers (AMF), including those listed in the Chapter 4 "Risk Factors" of AB Science reference document filed with the AMF on November 22, 2016, under the number R. 16-078. AB Science disclaims any obligation or undertaking to update the forward-looking information and statements, subject to the applicable regulations, in particular articles 223-1 et seq. of the AMF General Regulations.

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