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Masitinib Receives from European Medicines Agency (EMA) Orphan Drug Designation in the European Union for Amyotrophic Lateral Sclerosis (ALS)

AB Science SA (NYSE Euronext – FR0010557264 – AB), a pharmaceutical company specialized in the research, development and marketing of protein kinase inhibitors (PKIs), announces today that the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) granted orphan drug status to Masitinib product for the treatment of Amyotrophic Lateral Sclerosis (ALS), also known as Lou Gehrig's disease.

The granting of this orphan drug status in the EU is a significant milestone because it means that the COMP considered that Masitinib in combination with Riluzole generated significant benefit over Riluzole alone based on the results of the interim analysis of the on-going phase 2/3 of masitinib in ALS.

Indeed, the criteria to obtain orphan drug designation at EMA differ from those at FDA and are very stringent for the following reasons (refer to guidance EMA/COMP/15893/2009 Final for further details):

- Under EMA rules, in situations where there already exist authorized medicinal products, the sponsor should provide justification for the assumption that the medicinal product for which designation is sought will be of significant benefit to those affected by the condition.

- The application being based on an assumption of significant benefit, a comparison with authorized treatments is required.

- To follow the spirit of the Orphan legislation, which makes it clear that an orphan application may be made at any stage of the development, 'significant benefit' will be based on the available evidence at the stage of designation.

Because Riluzole is already authorized in ALS, AB Science had to provide justification that Masitinib will be of significant benefit in comparison with Riluzole, and because the designation was sought at the time interim results of the on-going phase 2/3 were available, the COMP had to consider whether Masitinib will be of significant benefit in comparison with Riluzole based on the results of this interim analysis.

AB Science provided to the COMP the data from the interim analysis of the on-going phase 2/3 in ALS. On this basis, the COMP recommended the orphan drug status designation, which means that the COMP considered that Masitinib is of significant benefit over existing therapy.

Alain Moussy, CEO of AB Science, said "*The granting of this orphan drug status is one more positive milestone from EMA after acceptance for the filing for conditional marketing authorization, still planned in September 2016*".

As a reminder, masitinib also received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for ALS.

About Orphan Drug Status Advantage

European Orphan Drug designation by the European Commission is granted to medicines intended for treatment of life‑threatening or chronically debilitating pathologies that affect no more than 5 in 10,000 people in the European Union (EU).

An orphan designation in the EU confers a range of benefits to sponsor companies including scientific advice on all aspects of product development at a reduced fee, direct access to the centralized procedure for marketing authorization, and eligibility for certain financial incentives made available by the Community and by the Member States to support research into and development of orphan drugs.

If the product is approved for marketing, the designation also provides 10 years of marketing exclusivity subsequent to product approval if the orphan designation still prevails at the time of marketing authorization.

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's 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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