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Masitinib Receives Orphan Drug Designation for Amyotrophic Lateral Sclerosis from FDA

AB Science SA (NYSE Euronext – FR0010557264 – AB), a pharmaceutical company specialized in research, development and marketing of protein kinase inhibitors (PKIs), announces that the U.S. Food and Drug Administration (FDA) has granted the company Orphan Drug designation for masitinib in the treatment of amyotrophic lateral sclerosis.

The FDA's Office of Orphan Drug Products Development reviews applications for Orphan Drug status to support development of medicines for underserved patient populations, or rare disorders that affect fewer than 200,000 people in the United States. The successful application submitted by AB Science and the FDA granting of Orphan Drug status entitles the company to a seven-year period of marketing exclusivity in the United States for masitinib, if it is approved by the FDA for the treatment of amyotrophic lateral sclerosis. Orphan Drug status also enables the company to apply for research grant funding for Phase I and II Clinical Trials, tax credits for certain research expenses, and a waiver from the FDA's application user fee, as well as additional support from FDA and a potentially faster regulatory process.

A phase 3 is currently on-going with masitinib in ALS. In January 2015, the external Data and Safety Monitoring Board (DSMB) recommended the continuation of this phase 3 study based upon review of the latest safety data. The DSMB was created as part of the Company's pivotal clinical study evaluating masitinib in the treatment of amyotrophic lateral sclerosis.

Amyotrophic lateral sclerosis is a rare degenerative disorder that results in progressive wasting and paralysis of voluntary muscles. There are approximately 30,000 people with ALS in the European Union and 15,000 in the US, with more than 7,500 new cases diagnosed each year in Europe and 4,500 in the US. Almost 50% of ALS patients die within 3 years and 90% die within 5 years.

About Orphan Drug Designation

The FDA Office of Orphan Products Development (OOPD) mission is to advance the evaluation and development of products (drugs, biologics, devices, or medical foods) that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions. In fulfilling that task, OOPD evaluates scientific and clinical data submissions from sponsors to identify and designate products as promising for rare diseases and to further advance scientific development of such promising medical products.

The approval of an orphan designation request does not alter the standard regulatory requirements and process for obtaining marketing approval for investigational use. Sponsors must establish safety and efficacy of a compound in the treatment of a disease through adequate and well-controlled studies. However, the FDA review process may be speedier for Orphan Drugs than those which do not receive Orphan Drug designation.

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 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 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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