



## Action plan following warning letter has been validated by FDA

**AB Science SA** (NYSE Euronext – FR0010557264 – AB), a pharmaceutical company specialized in the research, development and marketing of protein kinase inhibitors (PKIs), announces that the FDA informed AB Science that it trusts the action plan implemented to address the FDA warning letter and to comply with FDA regulations.

AB Science had received on June 16<sup>th</sup> 2015 a warning letter from the FDA following the inspection by this health authority of the monitoring of completed studies (refer to AB Science press release dated 14 July 2015).

AB Science responded in July 2015 to this warning letter with a proposed thorough corrective and preventive action plan.

The FDA reviewed this plan and has now responded to AB Science. In its letter, the FDA stated that *“We trust that the actions described in your letter will provide adequate measures to bring AB Science into compliance with FDA regulations”*.

Alain Moussy, CEO of AB Science, said *“This letter is an important operational and regulatory milestone vis-à-vis FDA. We are pleased to have received two positive news from the FDA recently. First we received the authorization of compassionate use of masitinib in Amyotrophic Lateral Sclerosis. Second, we received statement from FDA that it trusts AB Science complies with FDA regulation”*.

### 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 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, mastocytosis, 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](http://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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