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# AB Science announces new clinical results in oncology: Masitinib showed activity in metastatic melanoma bearing the juxta-membrane mutation of c-Kit

**AB Science SA** (NYSE Euronext - FR0010557264 - AB), today reports the analysis for its phase 3 trial evaluating masitinib in patients with non-resectable or metastatic stage 3 or stage 4 melanoma carrying a mutation in the juxta-membrane (JM) domain of c-Kit.

The phase 3 trial (AB08026) was an open-label, controlled study comparing masitinib to dacarbazine and designed to assess the safety and efficacy of masitinib 7.5 mg/kg/day in patients with non-resectable or metastatic stage 3 or stage 4 melanoma carrying a mutation in the juxta-membrane (JM) domain of c-Kit.

This form of melanoma is very rare and is estimated to account for less than 3% of melanoma patients. However, a tyrosine kinase inhibitor targeting the JM mutation of c-Kit could be beneficial for this population and complements current immunotherapy drugs.

The primary endpoint of the study was the Objective Response Rate (ORR).

In the course of the study, the recruitment in the dacarbazine arm was stopped for ethical reasons at the request of drug agencies. As such, the protocol was amended to evaluate the ORR for masitinib against a historical control (hypothesis of 15% response with dacarbazine).

In this study more than 500 patients were screened. A total of 30 patients were randomized with masitinib, including 23 (77%) in first line of treatment.

The ORR was 39.1% (p-value = 0.0012) in first line of treatment and 33.3% (p-value = 0.0049) regardless of the lines of treatment. There were two complete responses, including one complete response lasting for 1030 days.

These results confirm the activity of masitinib in tumors expressing JM-mutation of c-Kit and in metastatic cancer. AB Science has however decided to halt at this time the development of masitinib in this indication. The development of masitinib in oncology is focused on pancreatic cancer and prostate cancer, with phase 3 results expected in 2020.

## 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.

AB Science has developed a proprietary portfolio of molecules and the Company's lead compound, masitinib, has already been registered for veterinary medicine and is developed in human medicine in oncology, neurological diseases, and inflammatory diseases. 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 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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