

## Kinavet conditional approval has ended in the USA, pending the time to obtain full approval

Confirmatory study is ongoing in order to get full approval, with interim analysis already successful

AB Science is collaborating with the FDA to reinstate Kinavet under full approval

No financial impact on P&L in 2016

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 conditional approval of Kinavet has ended in the USA, pending the time to obtain full approval. The drug was conditionally approved in the USA for the treatment of non-resectable Grade II or III cutaneous mast cell tumors (MCT) in dogs that have not previously received radiotherapy and/or chemotherapy except corticosteroids.

Marketing of Kinavet will cease in the USA, pending full approval.

A confirmatory study (AB07008) is ongoing with expected recruitment of 150 dogs. This is a prospective, multicentre, randomized, placebo-controlled phase 3 study to compare efficacy and safety of masitinib to placebo in the treatment of aggressive mast cell tumors in dogs not previously treated by chemotherapy (other than corticosteroids) or radiotherapy.

An interim analysis based on the data from 74 dogs was successful. Masitinib showed statistically significant superiority on Time To Progression (Log-rank, p < 0.001). As recommended by the Food and Drug Administration (FDA), the study continues and the data remains blinded.

AB Science is collaborating with the FDA to complete the application in order to get full Kinavet approval in the USA in 2016.

In the USA, the end of conditional approval will have no impact on AB Science's P&L in 2016 since sales are at break-even point.

In Europe, the drug is fully approved by European Medicine Agency (EMA) under the brand name Masivet and AB Science will continue to market the drug.

## **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, T-cell lymphoma, mastocytosis, severe persistent asthma, 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: http://www.ab-science.com

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