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AB Science authorised to commercialise masitinib in the USA for treatment in canine mast cell tumor

AB Science SA (NYSE Euronext - FR0010557264 - AB), a pharmaceutical company specialising in the research, development and commercialisation of protein kinase inhibitors (PKIs), received today notification from the US Food and Drug Administration (FDA) that masitinib received conditional approval for treatment in canine mast cell tumor.

Masitinib will be made available to US veterinarians, for treatment of recurrent or nonresectable Grade II and Grade II cutaneous mast cell tumors in dogs that have not previously received radiotherapy and/or chemotherapy except corticosteroids. It will be marketed under the brand name KINAVET-CA1.

Masitinib was already approved by European Medicine Agency (EMA) and commercialised in Europe in treatment of canine mast cell tumor, under the name MASIVET.

Alain Moussy, Chairman and CEO of AB Science declared: « **This decision opens the USA market for masitinib in veterinary medicine, which is expected to be our largest market.** It is therefore a significant milestone. We thank FDA for this fruitful collaboration in oncology for unmet medical need and we will continue to collaborate closely with FDA to pursue the development of masitinib in the USA, both in veterinary and in human medicine ».

Dr Albert Ahn, President of AB Science USA commented « As we continue to generate further data, we are confident that we can establish masitinib as the reference treatment for canine mast cell tumors ».

About conditional approval and MUMS

In the USA, KINAVET-CA1 has been declared a designated new animal drug by FDA under the designation provision of the Minor Use Minor Species (MUMS) Act. This entitles KINAVET-CA1 to seven years of exclusive marketing rights beginning on the date of conditional approval. The conditional approval is a response to an application which demonstrated reasonable expectations of effectiveness. During the five year period of conditional approval, AB Science will continue to gather additional data to further support the safety and efficacy of masitinib in designated indication.

About Canine Mast Cell Tumor

Mast cell tumour (MCT), also known as a mastocytoma, is the most common cutaneous malignant neoplasm in dogs, accounting for 16 to 21% of all skin tumours. The behaviour and progression of MCTs are highly heterogeneous. They range from slow-growing tumours with a low potential for metastasis (grade I) to undifferentiated, aggressive tumours (grade II and III) with a high potential for metastasising to local lymph nodes, the liver, spleen and bone marrow

About masitinib

Masitinib is a new orally administered tyrosine kinase inhibitor that targets mast cells, important cells for immunity, as well as a limited number of kinases that play key roles in various cancers. Owing to its novel 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. Through its activity of inhibiting certain kinases that are essential in some oncogenic processes, masitinib may have an effect on tumour regression, alone or in combination with chemotherapy. Through its activity on the mast cell and certain kinases essential to the activation of the inflammatory cells and fibrosing tissue remodelling, masitinib can have an effect on the symptoms associated with some inflammatory and central nervous system diseases.

About AB Science

Founded in 2001, AB Science is a pharmaceutical company specialising in the research, development and commercialisation of protein kinase inhibitors (PKIs), a new class of targeted molecules whose action is to modify signalling pathways within cells. Through these PKIs, the Company targets diseases with high unmet medical needs (cancer, inflammatory diseases and central nervous system diseases), in both human and veterinary medicines. Thanks to its extensive research and development capabilities, AB Science has its own portfolio of molecules. Masitinib, a lead compound, has already been registered in veterinary medicine in Europe and is pursuing nine phase 3 studies in human medicine, including three studies on-going in pancreatic cancer, GIST and mastocytosis.

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 realisation 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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