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Masitinib decreases signs of canine atopic dermatitis Publication of phase 3 results in *Veterinary Dermatology*

AB Science SA (NYSE-Euronext, FR0010557264, AB), a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), announces the publication of results from its phase 3 clinical trial investigating the treatment of canine atopic dermatitis with masitinib in ***Veterinary Dermatology***, the lead journal in this field of research. The article entitled, '*Masitinib decreases signs of canine atopic dermatitis: a multicentre, randomized, double-blind, placebo-controlled phase 3 trial*', shows that masitinib has potential as an effective treatment of canine atopic dermatitis. Important facts about this study include:

- **Pivotal phase 3 study with one of the largest atopic dermatitis cohorts tested to date, 306 dogs**
- **Masitinib achieved statistically significant reduction in the signs of canine atopic dermatitis**
- **Positive response to masitinib was evident for dogs resistant or intolerant to ciclosporin and/or corticosteroids, and dogs with severe pruritus; two populations with high unmet medical need**
- **Masitinib could provide an important new tool in the veterinarian's armamentarium for effective treatment of canine atopic dermatitis**

The treatment of generalized canine atopic dermatitis remains a challenge, especially in severe or refractory cases. Beyond the already developed therapeutic strategies, there exists an unmet medical need to identify alternative treatments. Mast cells are known to produce a variety of inflammatory mediators that are in part responsible for the complex inflammatory cascade associated with allergic disease. As such, mast cells represent an attractive, hitherto untapped, therapeutic target for atopic dermatitis management. Masitinib, a selective oral tyrosine kinase inhibitor, effectively inhibits the survival, migration and activity of mast cells.

Dr. Pierre Cadot (DMV, Clinique vétérinaire Europa, France) the article's lead author declared: "*The key message from this study has to be that daily administration of oral masitinib achieved significant reduction in the signs of canine atopic dermatitis and could therefore be an effective treatment option. This positive response was evident not only in dogs that had never received treatment before but also in dogs resistant or intolerant to ciclosporin or corticosteroids, and dogs with severe pruritus, two groups representing populations with high unmet medical need*".

Dr. Patrick Hensel (DMV, DACVD, University of Georgia, USA) the study's coordinating investigator commented: "*This study was up to date one of the largest randomized, controlled clinical drug trials in the treatment of canine atopic dermatitis. Animals were carefully selected to meet the required criteria of atopic dermatitis. The findings of this study indicate that masitinib, which is selectively targeting mast cells, decreased clinical signs in the study population*".

This publication is available from the *Veterinary Dermatology* online library (<http://onlinelibrary.wiley.com/doi/10.1111/j.1365-3164.2011.00990.x/abstract>), and can be cited as: Cadot, P., Hensel, P., Bensignor, E., Hadjaje, C., Marignac, G., Beco, L., Fontaine, J., Jamet, J.-F., Georgescu, G., Campbell, K., Cannon, A., Osborn, S. C., Messinger, L., Gogny-Goubert, M., Dubreuil, P., Moussy, A. and Hermine, O. (2011), Masitinib decreases signs of canine atopic dermatitis: a multicentre, randomized,

double-blind, placebo-controlled phase 3 trial. *Veterinary Dermatology*, 22: no. doi: 10.1111/j.1365-3164.2011.00990.x. Publication in the paper version is scheduled for the coming months.

Full summaries of all masitinib-related veterinary publications are presented in the brochure 'Masitinib Scientific Data for Veterinary Medicine' (available upon request; contact@ab-science.com).

About canine atopic dermatitis

Atopic dermatitis is a chronic, pruritic inflammatory skin disease. Its severity can range from an annoyance in the form of mild itching through to debilitating extensive lesion coverage that has a profoundly negative impact on the quality-of-life. The prevalence of canine atopic dermatitis is poorly defined but it is well recognized that dogs suffering from this condition will be regularly presented to veterinary practitioners and that is likely to be a life-long condition. A commonly cited rate of incidence is 10%, whilst others have ranked it as the second most common cause of canine pruritus. Therapeutic options for treating generalized canine atopic dermatitis are currently limited to oral glucocorticoid steroids and calcineurin inhibitors such as oral ciclosporin. However, both are associated with numerous detrimental side effects and may be ineffective for a notable proportion of dogs (resistant or intolerant population).

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 tumor 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 remodeling, masitinib can have an effect on the symptoms associated with some inflammatory and central nervous system diseases.

About AB Science

AB Science is a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), a new class of targeted molecules whose action is to modify signaling 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. AB Science has developed its own portfolio of molecules including masitinib, which has already been registered in veterinary medicine in Europe and in the USA, and is pursuing nine phase 3 studies in human medicine, including five studies on-going in pancreatic cancer, GIST, in metastatic melanoma expressing JM mutation of c-Kit, in mastocytosis, and severe persistent asthma.

For further information: www.ab-science.com

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