

# Zoetis Launches Apoquel® - A Novel Dermatology Solution for Canine Pruritus

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## *First Janus Kinase Inhibitor Approved for Veterinary Use in Europe*

PARIS, FRANCE, January 29, 2014 – Zoetis Inc. announced today the launch of Apoquel® (oclacitinib maleate), a novel therapy indicated for the treatment of pruritus (itching) associated with canine allergic dermatitis and the clinical manifestations of atopic dermatitis. Veterinarians across Europe now have a first-in-class treatment choice that targets the itch of allergic skin conditions in dogs.

Apoquel is the first Janus Kinase (JAK) inhibitor approved for veterinary use. It provides rapid and sustained relief of pruritus and improves skin lesions without the side-effects associated with commonly-used therapies, such as glucocorticoids.

Canine pruritus is among the most frequent complaints of pet owners, affecting about one in six dogs whose owners seek veterinary help. About half of all itchy dogs will have an underlying allergic skin condition for which Apoquel would be indicated.

Pascal Prélaud, a dermatology specialist from Paris, who took part in the clinical development programme of Apoquel, said: "When a dog develops an itch related to an allergy, it can be life-disrupting for the dog and the entire family. I've learned firsthand the fundamental difference this treatment can make to a dog and its owners in stopping the itch, but without many of the side-effects that are common with steroids. Veterinarians now have an effective, well-tolerated choice to offer dog owners."

Apoquel has a unique and innovative mode of action, as it targets specific pathways of pruritus (itch) and inflammation, which makes it different to glucocorticoids. It is less likely to cause unwanted side-effects and also acts rapidly (demonstrating anti-pruritic efficacy within four hours) to reduce the itch, unlike cyclosporine which can take up to a month to control pruritus. "It will give me the time I need to find out what is causing the allergic dermatitis, to make a good diagnosis," Dr Prélaud added.

Dr Michael Stegemann, senior director of Veterinary Research and Development at Zoetis, said: "Zoetis is committed to providing treatments for conditions that affect the lives of pets and their owners who care for them."

"Apoquel is the culmination of more than a decade of dedication and ingenuity from Zoetis colleagues. We have been driven by our deep understanding of customers' unmet needs, and our determination that we can make a difference to the quality of life of pets and their caregivers. Apoquel, in my mind, epitomises why we exist: to apply our expertise in science and innovation, and deliver solutions to our customers."

**Apoquel Clinical Trial Results**

In clinical trials, Apoquel demonstrated a good safety profile and efficacy for the treatment of pruritus and resulted in improved skin lesions in dogs diagnosed with a number of allergic skin diseases as well as atopic dermatitis and treated either short or long term. The decrease in itch scores was observed by pet owners as soon as 24 hours after administration, the first observation time point, and pruritus continued to decrease compared to baseline until the end of the study. Skin lesions scores assessed by veterinarians were significantly improved after one week and continued to improve long term during the studies (four months).

In those field studies, the most common side-effects observed in dogs treated with Apoquel were vomiting and diarrhoea. Other reported side-effects included lethargy, decreased or lack of appetite, skin irritation or infection, and ear irritation or infection. The Apoquel safety profile is similar to placebo up to 16 days of treatment.

**About Apoquel**

Zoetis researchers have made major discovery findings around the mechanism of pruritus in allergic skin diseases, and the role of allergic, pro-inflammatory and itch cytokines that signal through the JAK pathway. Those findings supported the development of Apoquel.

While many current therapies are broad-based agents, Apoquel presents an innovative mode of action that allows targeting of pruritus and inflammation at its source when associated with allergic skin disease. It is an inhibitor of the JAK enzyme, a protein that is integral to the signalling pathway of cytokines that are pro-inflammatory or have a role in allergic and itch response.

Its novel mechanism of action on the JAK enzyme is specifically designed to target the pruritogenic and pro-inflammatory pathways involved in the itch cycle, allowing effective reduction of allergic itch regardless of its cause, and improvement of skin lesions associated with allergic skin diseases and atopic dermatitis.

Frequently used pruritus treatments have some drawbacks. In acute and chronic cases, steroids will effectively reduce pruritus, but their potential short-term side-effects (polydipsia, polyuria, polyphagia and panting) and potential long-term side complications (including pancreatitis, gastrointestinal ulceration, lipidemia, diabetes, muscle wasting and iatrogenic Cushing's syndrome) and often complex dosing schedules can be a real challenge to both dogs and their owners and limit their use.

Apoquel offers quick, effective, and sustained itch relief; it improves skin lesions and can be used for the short- or long-term.

Apoquel will be available on prescription by a veterinarian only. Apoquel tablets, dosed at 0.4 to 0.6 mg/kg, are administered orally, twice daily for up to 14 days, and then administered once daily for maintenance therapy if medium- to long-term treatment is required, such as in dogs with seasonal skin allergy and atopic dermatitis. Apoquel may be administered with or without food. During treatment with Apoquel, diagnosis and management of the underlying causes of the allergic dermatitis should be implemented as well. Apoquel has been used in conjunction with other medications including antibiotics, parasiticides and anti-inflammatories commonly used in dogs with skin diseases.

Apoquel is now available for veterinarians in Germany, Austria, Switzerland and will be available in other European countries in the upcoming weeks.

### **About Canine Pruritus Associated with Allergic Skin Disease**

Pruritus, or itch, is the most common sign of allergic skin disease in dogs. Itch associated with allergic skin diseases can occur on an acute, seasonal, or chronic basis - all of which can impact the quality of life of both the dog and its owner, unless it is rapidly and effectively controlled with symptomatic therapy.

### **About Zoetis**

Zoetis (zō-EH-tis) is the leading animal health company, dedicated to supporting its customers and their businesses. Building on a 60-year history as the animal health business of Pfizer, Zoetis discovers, develops, manufactures and markets veterinary vaccines and medicines complemented by diagnostic products and genetic tests and supported by technical services, with a focus on both farm and companion animals. In 2012, the company generated annual revenues of \$4.3 billion. With approximately 9,300 employees worldwide at the beginning of 2013, Zoetis has a local presence in approximately 70 countries, including 29 manufacturing facilities in 11 countries. Its products serve veterinarians, livestock producers and people who raise and care for farm and companion animals in 120 countries. For more information on the company, visit [www.zoetis.com](http://www.zoetis.com).

### DISCLOSURE NOTICE

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