

FDA Approves APOQUEL® (oclocitinib tablet) to Control Itch and Inflammation in Allergic Dogs

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Zoetis Offers a Targeted New Approach to Rapidly and Safely Stop the Cycle of Itch and Inflammation Associated with Allergic Skin Disease in Dogs

MADISON, N.J.--(BUSINESS WIRE)--Zoetis, Inc. (NYSE: ZTS), formerly the animal health business unit of Pfizer Inc., today announced that the U.S. Food and Drug Administration (FDA) has approved APOQUEL® (oclocitinib tablet) for the control of pruritus associated with allergic dermatitis and the control of atopic dermatitis in dogs at least 12 months of age. Pruritus, or itching, is the most common sign of allergies in dogs. Developed by Zoetis, APOQUEL is the first Janus kinase (JAK) inhibitor approved for veterinary use that targets the itch and inflammation pathway. APOQUEL provides fast-acting relief from itching and improves inflammation for the estimated 8.2 million dogs that suffer from short- and long-term allergic skin conditions.

"Previously available treatments have helped with the management of allergic skin disease in dogs, but an unmet need still exists for a treatment that works rapidly and effectively with minimal short- and long-term side effects," said Douglas DeBoer, DVM, DACVD, Professor of Dermatology at the University of Wisconsin-Madison School of Veterinary Medicine, an expert in veterinary dermatology and allergy. "The approval of APOQUEL is encouraging because it will provide both veterinarians and pet owners with a treatment that reduces itch within hours and provides long term relief of itching and inflammation for dogs without the side effects of steroids."

Atopic dermatitis is one of the most common allergies in dogs, affecting approximately 10 percent of the dog population. Itching caused by an allergic skin disease can be an acute, short-term condition or can be recurrent or chronic—all which can impact the quality of life for both the dog and its owner unless they are controlled with effective management.

APOQUEL Clinical Trial Results

FDA approval of APOQUEL is based on results of two clinical trials conducted in the United States which showed that APOQUEL was effective in the treatment of pruritus associated with allergic dermatitis and for the control of atopic dermatitis. In a trial of dogs with allergic dermatitis, treatment success, as defined by owner-assessed decrease in pruritus, occurred in 67 percent of dogs treated with APOQUEL vs. 29 percent of dogs treated with placebo after one week of treatment. In both studies, dogs that remained on APOQUEL beyond one week experienced continuous improvement throughout the course of the study. The frequency and type of adverse events were similar between APOQUEL- and placebo-treated dogs in short-term trials. Minimal adverse events were reported in multiple long-term trials.

In a clinical trial of dogs with atopic dermatitis, treatment success for pruritus occurred in a significantly greater percentage of the dogs treated with APOQUEL (66 percent) vs. (4 percent) of dogs treated with placebo ($p < 0.0001$). APOQUEL effectively reduced both owner-assessed itch and veterinarian-assessed dermatitis throughout the course of the study.

In clinical studies, the most common side effects observed in dogs treated with APOQUEL were vomiting and diarrhea. Other reported side effects included: lethargy, decreased or lack of appetite, skin irritation or infection, and ear irritation or infection. APOQUEL may increase the susceptibility to infection and demodicosis and may exacerbate neoplastic conditions.

About APOQUEL

While most current therapies are broad-based agents, APOQUEL is uniquely targeted to stop the itch and inflammation associated with allergic skin disease. It is a selective inhibitor of the Janus kinase (JAK) 1 enzyme, a protein that is integral to the signaling pathway that results in itching and inflammation. Its novel mechanism of action on the JAK enzymes is specifically designed to target the pruritogenic and proinflammatory pathways involved in the itch cycle, allowing control of the signs of allergic disease.

Current treatments for allergic skin disease are limiting. In acute and chronic cases of allergic dermatitis, steroids may effectively reduce pruritus, but the short- and long-term side effects (including polydipsia, polyphagia, polyuria, pancreatitis, gastrointestinal ulceration, lipidemias, diabetes, muscle wasting and iatrogenic Cushing's syndrome) and intricate dosing schedules can be challenging to dogs and their owners.

"The approval of APOQUEL provides a much-needed, new, targeted treatment choice for dogs that suffer from allergic skin conditions and affords the damaged skin an opportunity to heal, while allowing the veterinarian ample time to identify the underlying cause of a dog's allergic disease," said Catherine Knupp, Executive Vice President and President, Research and Development at Zoetis. "Zoetis is committed to research and development programs that address the real world

challenges veterinarians face while serving the unmet needs of our veterinary customers in better ways.”

Discovered and developed by Zoetis, APOQUEL will be available by prescription only. APOQUEL tablets, dosed at 0.18 to 0.27 mg per pound (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. APOQUEL may be administered with or without food.

Zoetis plans to make APOQUEL available to veterinarians by the First Quarter 2014. During the coming months, Zoetis will be educating veterinarians on the new science associated with canine allergic diseases to lay the groundwork for a successful launch. For more information, please visit www.Apoquel.com. As the latest addition to the company's diverse portfolio of companion animal medicines, this approval signifies an important milestone for this leading animal health company.

About Zoetis

Zoetis (zō-EH-tis) is the leading animal health company, dedicated to supporting customers and businesses focused on raising and caring for livestock and companion animals. 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 a range of services. The company generated annual revenues of \$4.3 billion in 2012. It has more than 9,300 employees worldwide and 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 livestock and companion animals in 120 countries. For more information, visit www.zoetis.com or www.zoetisus.com.

Important Safety Information

APOQUEL® should not be used in dogs less than 12 months of age or in dogs with serious infections. APOQUEL may increase the susceptibility to infection and demodicosis and may exacerbate neoplastic conditions. APOQUEL has not been evaluated in combination with systemic immunosuppressive agents such as glucocorticoids or cyclosporine. APOQUEL should not be used in breeding dogs, or pregnant or lactating dogs. The most common side effects seen in dogs administered APOQUEL were vomiting and diarrhea. APOQUEL has been safely used in conjunction with other common medications including antibiotics and parasiticides and with vaccinations.

DISCLOSURE NOTICE

Forward-Looking Statements: This news release contains forward-looking statements. These forward-looking statements address various matters including information about Zoetis products. Each forward-looking statement contained in this news release is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others, regulatory actions and timing of any new product launches; competitive pressures, environmental trends and conditions; and the risks identified under the heading "Risk Factors" in our Annual Report on Form 10-K for 2012, which was filed with the Securities and Exchange Commission on March 28, 2013, as well as the other information we file with the SEC. We caution investors not to place considerable reliance on the forward-looking statements contained in this news release. You are encouraged to read our filings with the SEC, available at www.sec.gov, for a discussion of these and other risks and uncertainties. The forward-looking statements in this news release speak only as of the date of this document, and we undertake no obligation to update or revise any of these statements. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

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