BRAVECTO® PLUS (fluralaner and moxidectin topical solution) for Cats Receives Approval from US Food and Drug Administration

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Extended Duration Formulation Ensures Cats Receive Broad-Spectrum Parasite Coverage in One Topical Application

MADISON, N.J.--(BUSINESS WIRE)--Merck Animal Health, a division of Merck & Co., Inc., Kenilworth, N.J., USA (NYSE: MRK), today announced the U.S. approval of BRAVECTO® PLUS topical solution for cats by the U.S. Food and Drug Administration (FDA). BRAVECTO PLUS is an extended-duration, broad-spectrum combination (fluralaner and moxidectin) topical solution for cats, indicated for both external and internal parasite infestations: ticks and fleas, heartworm, intestinal roundworm and hookworm. This unique formula in BRAVECTO PLUS provides extended protection for up to two months with just one application, making it the only product on the market to protect against this combination of parasites at a longer duration. BRAVECTO PLUS is expected to be available in the coming months.

“BRAVECTO PLUS addresses five of the top parasite concerns among veterinarians and cat owners, including ticks, fleas, heartworms, roundworms and hookworms,” said Christine Royal, DVM, director, Professional Services at Merck Animal Health. “These parasites are not just a nuisance, but also pose animal and human health risks. Ticks and fleas can transmit disease; and heartworm disease, transmitted by mosquitoes, is a serious, progressive disease that often goes undiagnosed in cats. We are pleased to offer cat owners the latest innovation from the BRAVECTO family.”

“With BRAVECTO PLUS for cats, we have expanded our portfolio in the fight against parasites by creating an extended duration formulation, ensuring pets receive the broad-spectrum parasite coverage,” Dr. Royal said.

BRAVECTO PLUS contains fluralaner (280 mg/mL), an ectoparasiticide which has systemic activity against ticks and fleas, and moxidectin (14 mg/mL), an endectocide which has systemic activity against a range of external and internal parasites.

BRAVECTO PLUS treats fleas and ticks fast, killing 100 percent of fleas and more than 99.7% of ticks in the first 12 hours after the product is applied. This protection works quickly and lasts. Additionally, roundworm is the most common feline intestinal parasite, affecting up to 75% of cats, and is also effectively treated with BRAVECTO PLUS. The quality of extended-duration treatment with BRAVECTO PLUS helps to improve compliance among pet owners, which may lead to healthier cats.

BRAVECTO PLUS is part of the Merck Animal Health pet health portfolio, which includes Sure Petcare, a range of digitally connected products.

About BRAVECTO® PLUS

BRAVECTO ® PLUS is indicated for the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment of infections with intestinal roundworm (*Toxocara cati*; 4th stage larvae, immature adults and adults) and hookworm (*Ancylostoma tubaeforme*; 4th stage larvae, immature adults and adults). BRAVECTO PLUS kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of tick infestations (*Ixodes scapularis*; black-legged tick) and *Dermacentor variabilis*; (American dog tick) for 2 months in cats and kittens 6 months of age and older and weighing 2.6 lb. or greater.

About BRAVECTO® (fluralaner)

Since its introduction in 2014, BRAVECTO has provided longer-lasting flea and tick protection, with more than 100 million doses distributed in 85 countries over five years. BRAVECTO is available in a variety of formulations, including products for both dogs and cats.

The flea lifecycle can last as long as 12 weeks, and monthly treatments may leave gaps in protection. One treatment with BRAVECTO lasts 12 weeks, protects almost three times longer than monthly treatments and is proven to kill fleas on dogs.
and cats and to eliminate them from the home.5

Providing pets with continuous flea and tick protection is essential – whether the pet goes outside or not. Contrary to popular belief among pet owners, fleas and ticks are not only active in the spring and summer months and are a year-round risk.

Fleas and ticks can easily latch onto dogs and cats, and can spread serious diseases, including tapeworms and Lyme disease. They also can bite and pose health risks to human family members whether at home or outdoors. Fleas are the most common external parasite found on pets.

BRAVECTO products are only available through licensed veterinarians.

BRAVECTO has not been shown to be effective for 12-weeks duration in puppies or kittens less than 6 months of age. BRAVECTO Chew: The most commonly reported adverse reactions include vomiting, decreased appetite, diarrhea, lethargy, polydipsia and flatulence. BRAVECTO is not effective against long star ticks beyond 8 weeks of dosing.

BRAVECTO Topical Solution for Dogs: The most commonly reported adverse reactions include vomiting, hair loss, diarrhea, lethargy, decreased appetite and moist dermatitis/rash. BRAVECTO is not effective against long star ticks beyond 8 weeks of dosing. For topical use only. Avoid oral ingestion. Use caution in dogs with a history of seizures. Seizures have been reported in dogs receiving fluralaner, even in dogs without a history of seizures. BRAVECTO Topical Solution for Cats: The most commonly reported adverse reactions include vomiting, itching, diarrhea, hair loss, decreased appetite, lethargy and scabs/ulcerated lesions. BRAVECTO is not effective against American dog ticks beyond 8 weeks of dosing. For topical use only. Avoid oral ingestion. The safety of BRAVECTO has not been established in breeding, pregnant and lactating cats. Use with caution in cats with a history of neurologic abnormalities. Neurologic abnormalities have been reported in cats receiving BRAVECTO, even in cats without a history of neurologic abnormalities.

Important Safety Information about BRAVECTO PLUS spot-on solution for Cats

The most commonly reported adverse reactions include vomiting, hair loss, itching, diarrhea, lethargy, dry skin, elevated ALT, and hypersalivation. BRAVECTO PLUS has not been shown to be effective for 2 months in kittens less than 6 months of age. For topical use only. Avoid oral ingestion. The safety of BRAVECTO PLUS has not been established in breeding, pregnant and lactating cats. Fluralaner is a member of the isooxazoline class. This class has been associated with neurologic adverse reactions including tremors, ataxia, and seizures. Neurologic adverse reactions have been reported in cats receiving isooxazoline. Use with caution in cats with a history of neurologic abnormalities. Use with caution in cats that are heartworm positive. The effectiveness of BRAVECTO PLUS to prevent heartworm disease after bathing or water immersion has not be evaluated.

About Merck Animal Health

For more than a century, Merck, a leading global biopharmaceutical company, has been inventing for life, bringing forward medicines and vaccines for many of the world’s most challenging diseases. Merck Animal Health, a division of Merck & Co., Inc., Kenilworth, N.J., USA, is the global animal health business unit of Merck. Through its commitment to The Science of Healthier Animals®, Merck Animal Health offers veterinarians, farmers, pet owners and governments one of the widest ranges of veterinary pharmaceuticals, vaccines and health management solutions and services as well as an extensive suite of digitally connected identification, traceability and monitoring products. Merck Animal Health is dedicated to preserving and improving the health, well-being and performance of animals and the people who care for them. It invests extensively in dynamic and comprehensive R&D resources and a modern, global supply chain. Merck Animal Health is present in more than 50 countries, while its products are available in some 150 markets. For more information, visit www.merck-animal-health.com or connect with us on LinkedIn, Facebook and Twitter.

About Sure Petcare

Sure Petcare, the pet technology specialist, provides pet products that empower owners to care for their pets in entirely new ways. Founded in 2007, we have developed an award-winning range of microchip-operated pet doors and feeders, which solve many problems commonly experienced by pet owners. Sure Petcare, along with HomeAgain, is a Companion Animal portfolio of digital products within Merck Animal Health.

Recently in the United States, Sure Petcare launched the SureFeed Microchip Pet Feeder Connect, the next generation of the best-selling SureFeed Microchip Pet Feeder, which monitors the eating behavior of pets. The smart feeder monitors how much and when a pet eats, sending real-time updates directly to the pet owner’s phone. The new product also features integrated scales, which enable owners to provide accurate food portions to their pet at every meal.

For more information, visit www.surepetcare.com.

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the “company”) includes “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company’s management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company’s ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of
the company’s patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company’s 2018 Annual Report on Form 10-K and the company’s other filings with the Securities and Exchange Commission (SEC) available at the SEC’s Internet site (www.sec.gov).

Please see Prescribing Information for BRAVECTO® at www.us.bravecto.com.

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