First and only FDA-approved treatment calms without sedating

FLORHAM PARK, N.J.--(BUSINESS WIRE)--Dogs that experience fear and anxiety in response to loud noise such as fireworks, thunder, and construction work now have a new treatment option with the launch of SILEO® (dexmedetomidine oromucosal gel), the first and only medication approved by the U.S. Food and Drug Administration (FDA) for treatment of noise aversion in dogs. Noise aversion refers to the behavioral and clinical signs of fear and anxiety experienced by dogs in response to noise. SILEO, which is being marketed in the U.S. by Zoetis Inc. (NYSE:ZTS), is available from veterinarians by prescription and can be safely administered at home by pet owners to help calm dogs without sedating for the duration of noise events.

“We know that noise aversion has been difficult to treat, is stressful for pet owners and can be traumatic for their dogs. SILEO works the way veterinarians and pet owners need it to work, calming dogs while allowing them to interact normally with the family,” said Shelley L. Stanford, DVM, MS, MBA, group director, Companion Animal Veterinary Professional Services at Zoetis. “It has rapid speed of onset, is easy to administer at home and works ‘in the moment,’ without any other treatments or training. We are proud to bring this innovation to veterinarians and the pet owners and dogs who count on them.”

SILEO is an oromucosal gel formulation of dexmedetomidine, a highly selective alpha-2 adrenoceptor agonist that blocks norepinephrine release, a chemical in the brain that is involved with the development of fear and anxiety. SILEO is administered via oral transmucosal absorption, limiting the amount of dexmedetomidine available in the body at any given time after administration and thereby providing a calming effect without sedating. This allows dogs with noise aversion to remain calm yet fully functional. In addition, SILEO has a rapid speed of onset that can be tailored to the timing and duration of noise events. It works on its own without any other treatments or training.

About Noise Aversion

At least one-third of pet owners report that their dog suffers from noise aversion. Common clinical signs include panting, trembling, cowering, and escape behavior, which can result in self-trauma as well as property damage. These behaviors indicate the dog’s distress and disrupt the human-animal bond during noise events, such as July 4th celebrations. In fact, fireworks are one of the top triggers for noise aversion in dogs and, as a result, July 5th is the busiest day for shelter intakes in the United States. However, only 40 percent of pet owners seek treatment from their veterinarian; 20 percent look for solutions on their own, while the remaining 40 percent of dogs suffering from noise aversion do not receive any treatment.

Currently, 69 percent of pet owners are “neutral” to “dissatisfied” with the current treatment options: the unmet need is a treatment that provides consistent results without causing sedation or requiring behavior modification. Behaviorists agree that untreated noise aversion progresses to a more severe state and the development of other anxieties.

“There is no suffering and pain worse for dogs than that caused by fear. Fear deprives dogs of joy and damages relationships,” says Karen L. Overall, MA, VMD, PhD, Diplomate American College of Veterinary Behavior, of Philadelphia, PA. “Fears of noises may affect almost half of all dogs in their lifetimes. It is one of the most common co-morbid canine behavioral conditions, and it worsens other behavioral conditions. Behavioral pathology is progressive, so early recognition, diagnosis and treatment are essential. Every effort to minimize or mitigate fearful states is essential to humane care.”

About SILEO

Veterinarians prescribe SILEO in a 3mL high-density polyethylene syringe, equipped with a dosing ring and end cap and packaged in a cardboard box. The dosage is 125 mcg/m². It is administered by placing the gel between the dog’s cheek and gum and allowing for oral transmucosal absorption. In a usability study, over 90 percent of pet owners assessed the usability of the syringe to be “easy” or “very easy” to eject the correct volume of gel.

SILEO typically takes effect within 30-60 minutes after application. The first dose can be given as soon as the dog shows signs of anxiety and fear, or approximately 30–60 minutes before a known anxiety- or fear-causing noise stimulus, such as fireworks. Each dose will last between two to three hours. SILEO can be re-dosed as needed every two hours, up to five times during each noise event. The pre-filled applicator has between one and 12 doses, depending on the size of the dog.

SILEO has been demonstrated to be safe and effective in two randomized, double-blinded clinical field studies. SILEO had a good or excellent effect in 75 percent of the dogs which was significantly different from the placebo at p<0.0001. Adverse
reaction rate to SILEO was low, and all reactions were mild. Zoetis markets and distributes SILEO in the U.S. under exclusive agreement with Orion Corporation, Orion Pharma Finland, which developed and manufactures SILEO.

SILEO will be available to order within one week. For more information about SILEO, please visit www.sileodvmus.com or call Zoetis Customer Service at 1-888-Zoetis1 (1-888-963-8471).

**IMPORTANT SAFETY INFORMATION**

Do not use SILEO in dogs with severe cardiovascular disease, respiratory, liver or kidney diseases, or in conditions of shock, severe debilitation or stress due to extreme heat, cold or fatigue or in dogs hypersensitive to dexmedetomidine or to any of the excipients. SILEO should not be administered in the presence of preexisting hypotension, hypoxia or bradycardia. Do not use in dogs sedated from previous dosing. SILEO has not been evaluated in dogs younger than 16 weeks of age or in dogs with dental or gingival disease that could have an effect on the absorption of SILEO. SILEO has not been evaluated for use in breeding, pregnant or lactating dogs. Transient pale mucous membranes at the site of application may occur with SILEO use. Other uncommon adverse reactions included emesis, drowsiness or sedation. Handle gel-dosing syringes with caution to avoid direct exposure to skin, eyes or mouth. For full Prescribing Information, go to ZoetisUS.com/SileoPI.

**About Zoetis**

Zoetis (zô-EH-tis) is the leading animal health company, dedicated to supporting its customers and their businesses. Building on more than 60 years of experience in animal health, Zoetis discovers, develops, manufactures and markets veterinary vaccines and medicines, complemented by diagnostic products and genetic tests and supported by a range of services. Zoetis serves veterinarians, livestock producers and people who raise and care for farm and companion animals with sales of its products in more than 100 countries. In 2015, the company generated annual revenue of $4.8 billion with approximately 9,000 employees. For more information, visit www.zoetis.com.

**DISCLOSURE NOTICES**

**Forward-Looking Statements:** This press release contains forward-looking statements, which reflect the current views of Zoetis with respect to business plans or prospects, future operating or financial performance, future guidance, future operating models, expectations regarding products, future use of cash and dividend payments, tax rate and tax regimes, changes in the tax regimes and laws in other jurisdictions, and other future events. In particular, this press release contains forward looking statements that reflect the current views of Zoetis with respect to our tax rate and tax regimes, changes in the tax regimes in other jurisdictions and challenges to our efforts to mitigate the impact of tax decisions such as the recent one by the European Commission. These statements are not guarantees of future performance or actions. Forward-looking statements are subject to risks and uncertainties. If one or more of these risks or uncertainties materialize, or if management’s underlying assumptions prove to be incorrect, actual results may differ materially from those contemplated by a forward-looking statement. Forward-looking statements speak only as of the date they are made. Zoetis expressly disclaims any obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. A further list and description of risks, uncertainties and other matters can be found in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, including in the sections thereof captioned “Forward-Looking Information and Factors That May Affect Future Results” and “Item 1A. Risk Factors,” in our Quarterly Reports on Form 10-Q and in our Current Reports on Form 8-K. These filings and subsequent filings are available online at www.sec.gov, www.zoetis.com, or on request from Zoetis.

**References**

1. Based on an online survey conducted by Harris Poll on behalf of Zoetis in November 2013 among 784 dog owners.

2. FR Market Research - Noise Aversion; February 2016; N=472 Dog Owners, N=454 General Practitioners.


4. SILEO (dexmedetomidine oromucosal gel) NADA 141-456 Freedom of Information Summary.

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**Contact:**

Zoetis
Media:
Elinore White, 973-443-2835 (o)
elinore.v.white@zoetis.com
Ticker Slug:
Ticker: ZTS
Exchange: NYSE

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