European Commission Grants Marketing Authorisation to Simparica Trio™, a Once-Monthly Triple Combination Antiparasitic Medication for Dogs

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• Gives veterinarians a new choice for the treatment of mixed external and internal parasitic infestations
• Treats and has persistent efficacy against ticks and fleas for one month
• Treats gastrointestinal nematodes
• Prevents heartworm disease (Dirofilaria immitis) and lungworm disease (Angiostrongylus vasorum)

PARSIPPANY, N.J.--(BUSINESS WIRE)--Zoetis Inc. (NYSE:ZTS) today announced that the European Commission has granted marketing authorisation for Simparica Trio™ (sarolaner/moxidectin/pyrantel) chewable tablets, a once-monthly triple combination antiparasitic medication for dogs with, or at risk from, mixed external and internal parasitic infestations. The granting of the marketing authorisation follows a positive opinion adopted by the Committee for Medicinal Products for Veterinary Use on July 18, 2019.

“The approval of Simparica Trio™ provides veterinarians a safe and effective option for the treatment of mixed external and internal parasitic infestations in dogs in the form of a new oral chewable,” said Dr. Domenico Otranto1, DVM, PhD, DipEVPC, Professor in Veterinary Parasitology at the University of Bari (Italy). “Simparica Trio has been shown to rapidly kill fleas and ticks with concurrent efficacy for the prevention of heartworm disease and angiostrongylosis (lungworm disease) and treatment of intestinal round- and hookworms. The convenience of a once monthly chewable tablet helps increase compliance with treatment, giving veterinarians and dog owners confidence in continuous protection.”

“We are excited to bring Simparica Trio to veterinarians in the European Union as a new, effective triple combination parasiticide for dogs,” said Dr. Catherine Knupp, Executive Vice President and President, Research and Development at Zoetis. “This innovative product is a result of the collaboration of Zoetis scientists worldwide, who share a determination to develop new medicines that deliver real value to our veterinary customers and the animals in their care. The addition of this new, broad spectrum parasiticide to our sarolaner range of products helps to tailor the antiparasitic treatment of pets to their individual needs.”

The global canine parasiticides market is more than $4 billion US dollars2, and is the largest therapeutic category in medicines for dogs.

Simparica Trio demonstrates Zoetis’ continued innovation in parasiticides

The active ingredients of Simparica Trio are: sarolaner, which is active against fleas and ticks; moxidectin, effective against heartworm, lungworm and some intestinal worms; and pyrantel embonate, effective against gastrointestinal nematodes (hookworms and roundworms).

Simparica Trio was shown to provide immediate and persistent killing activity for five weeks against two species of fleas (*Ctenocephalides felis* and *C. canis*) and the ticks *bodes hexagonus*, *bodes ricinus* and *Rhipicephalus sanguineus* and for four weeks against *Dermacentor reticulatus*. It demonstrated a rapid onset of action, killing fleas before they have a chance to lay eggs and can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis. In addition, Simparica Trio is indicated for the prevention of heartworm disease (*Dirofilaria immitis*) and lungworm disease (*Angiostrongylus vasorum*) and the treatment of gastrointestinal roundworm and hookworm infections of *Toxocara canis* (immature adults (L5) and adults); *Ancylostoma caninum* (L4 larvae, immature adults (L5) and adults); *Toxascaris leonina* (adults); and *Uncinaria stenocephala* (adults). Simparica Trio’s spectrum includes immature *A. caninum* and *T. canis* which is important in controlling environmental contamination and minimizing human exposure to these zoonotic parasites. The marketing authorization for Simparica Trio was based on the results of veterinary patient studies conducted in eight countries, involving more than 1900 dogs of various breeds. The product is indicated for dogs from at least eight weeks of age and 1.25 kg of bodyweight.
Zoetis expects to launch Simparica Trio in the EU in the first quarter of 2020. Simparica Trio chewable tablets will be available in six tablet strengths for dogs of all sizes.

For more information about Simparica Trio and full prescribing information, visit www.zoetis.com. For more information about the European Commission’s marketing authorization click here.

About Zoetis

Zoetis is the leading animal health company, dedicated to supporting its customers and their businesses. Building on more than 65 years of experience in animal health, Zoetis discovers, develops, manufactures and commercializes medicines, vaccines and diagnostic products, which are complemented by biodevices, genetic tests and 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 2018, the company generated annual revenue of $5.8 billion with approximately 10,000 employees. For more information, visit www.zoetis.com.

About internal and external parasites

Beyond being a burden by feeding off the blood of infested dogs, fleas and ticks can be carriers of vector borne diseases to other dogs which can be very debilitating and difficult to treat. Larvae from certain gastrointestinal worms may be shed in the environment and pose a threat of zoonotic disease to humans while both heartworm (D.immitis) and lungworm (A.vasorum) disease can be fatal to affected dogs. (ESCCAP)³

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, expectations regarding products, regulatory approvals and other future events. 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 on which 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, 2018, including in the sections thereof captioned “Forward-Looking Statements 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.

¹ Dr. Domenico Otranto, is a consultant to Zoetis Inc.
² Based on internal estimates

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