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Tildren® (tiludronate disodium) Receives FDA Approval to Control Clinical Signs of Navicular Syndrome

Lenexa, Kan. (December 22, 2014) — Equine veterinarians now have an important new tool to help them manage navicular syndrome in patients. Tildren® (tiludronate disodium), a novel product that has been available in some international markets for more than 12 years, is now FDA-approved and available to U.S. veterinarians.

With the recent FDA approval, Ceva Animal Health will begin selling Tildren in the U.S. in early December. Approved to control clinical signs associated with navicular syndrome in horses, Tildren will be available for veterinarians to purchase through national distribution channels.

Tildren has been used worldwide for more than 12 years with more than 250,000 doses administered. Some U.S. veterinarians are already familiar with the product due to its use in international markets. Now that it is approved by FDA, Tildren will be readily available to U.S. veterinarians and easy for them to obtain.

"Navicular syndrome is the most common cause of chronic forelimb lameness in horses," says Steve, Hoffman, Vice President of Ceva's Equine Business Unit. "The approval of Tildren by the FDA provides veterinarians and horse owners an excellent new tool for managing navicular syndrome."

The primary action of Tildren is to regulate osteoclasts in areas of excessive activity. In navicular syndrome, excessive mechanical stress results in bone resorption outpacing bone formation. Tildren works at areas of active bone resorption, restoring balance to the process of bone remodeling.

"Tildren is a novel therapy that can lead to successful outcomes even when clinical signs have not improved with other therapies," said Kyle Creech, DVM, Ceva's Equine Veterinary Services Manager. "Our equine sales team is made up entirely of veterinarians who have experience treating patients with Tildren. This team is well versed in the use of this product and can help provide advice and support that will help lead to successful treatment."

See full prescribing information for more information. To learn more about Tildren, contact your Ceva representative or call 800-999-0297.

Do not use in horses with impaired renal function or with a history of renal disease. **NSAIDs should not be used concurrently with Tildren. Concurrent use of NSAIDs with Tildren may increase the risk of renal toxicity and acute renal failure.** Horses should be observed closely for 4 hours post-infusion for the development of clinical signs consistent with colic or other adverse reactions. Caution should be used when administering Tildren to horses with conditions affecting mineral or electrolyte homeostasis (e.g. HYPP, hypocalcemia) and conditions which may be exacerbated by hypocalcemia (e.g. cardiac disease). The safe use of Tildren has not been evaluated in horses less than 4 years of age, in pregnant or lactating mares, or in breeding horses.

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About Ceva Animal Health: Ceva's other key equine products include Altresyn® (altrenogest) and Confidence EQ®. Other companion animal products include the Vectra® line of parasiticides, ADAPTIL® and FELIWAY® pheromone behavior aids and Senilife® neuroprotection for aging pets. Ceva's North America Zone headquarters is located in Lenexa, Kansas. Visit www.ceva.us.

About Ceva Santé Animale: Ceva's parent company is a global veterinary health company focused on the research, development, production and marketing of pharmaceutical products and vaccines for pets, livestock, swine and poultry. The global headquarters is located in Libourne, France. <u>Visit www.ceva.com</u>