



For Immediate Release

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CARDALIS™ Receives U.S. Approval

(July 2020 – Lenexa Kan.) The U.S. Food and Drug Administration has approved CARDALIS for the U.S. market. This concludes a 12-year registration process for the U.S. team.

“Human-approved benazepril and spironolactone products have historically been used to treat Atrioventricular Valvular Insufficiency (AVVI) or mitral valve disease in U.S. dogs. CARDALIS is novel in the U.S. market because the drugs are now approved for canine patients and in a combination shown to be safe and effective”, said Dr. Melissa Coffman who was responsible for the safety and efficacy studies. “Being a combination tablet that is flavored and chewable makes administering the medications to these very sick dogs easier. One less pill to give and easier for owners means better compliance.”

Enrollment in the clinical trial ultimately resulted in the largest veterinary cardiology trial to date. It was a pivotal field effectiveness study for the U.S. A total of 569 dogs being treated in 27 specialty clinics across the U.S. were enrolled.

The complex field study took a long time to initiate and execute. The team sought a very specific group of dogs who were at a late stage in the progression of the disease. The team followed each of these dogs for up to a year. Because of the number of dogs needed it took four and a half years to find eligible dogs and complete the necessary research.

CARDALIS is the first non-generic, new, companion animal drug FDA approved by Ceva’s U.S. team. This is a huge accomplishment for the entire team to be proud about. New animal drug approvals take an average of 7-10 years in the U.S.

It took a large team to accomplish this registration: Congratulations to the U.S. Regulatory and Development teams overseen by Garret Newbound: Alicia Henk, Lori Daniel, Melissa Coffman, Tiffany Laclair and Katy Hernandez, as well as the many people who supported the project along the way including Carol Ferguson, Dominique Thibaud, Florence Bernay, Emilie Guillot, Catherine Garelli-Paar, Spark Feng and Thomas Blondel.

“This approval is a result of the work and dedication of a global development team. We thank numerous people for their contributions. However, the real winners are the dogs and their pet-parents who now have a new approach to treating congestive heart failure due to atrioventricular valvular insufficiency”.
Garret Newbound, DVM, PhD Director of Development and Regulatory Affairs, Ceva Animal Health.

The U.S. commercial team has been preparing for the launch of the product which will likely take place in the fourth quarter.

Ceva launched CARDALIS in Europe during 2012, while the product was approved by the Australian Pesticides and Veterinary Medicines Authority in 2016.

Full product information can be found as part of the FDA's product release:

[FDA Approves Cardalis for the Management of Congestive Heart Failure in Dogs | FDA](#)

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