RAPACAT FELINE HYPERTROPHIC CARDIOMYOPATHY FIELD STUDY

Feline hypertrophic cardiomyopathy (HCM) is a life-threatening progressive disease affecting up to 15% of cats.[1] Despite the devastatingly high morbidity and mortality rates associated with HCM, it remains a disease with little therapeutic advancement. [2]TRIV202's active ingredient modulates the mTOR pathway, preventing and reversing cardiac hypertrophy in rodent disease models.[3]Its use in human renal allograft patients is associated with reduced cardiac wall thickness.[4] In collaboration with two US academic centers, TriviumVet sought to evaluate the effects of six months of once-weekly dosing with TRIV202 on echocardiographic, biochemical, and biomarker responses in cats with subclinical HCM.

Forty-three client-owned cats with subclinical HCM (Stage B1 & B2) were enrolled in a double-blinded, multicenter, randomized, and placebo-controlled clinical trial. Cats were allocated to low- or high-dose TRIV202 or placebo. Cats underwent physical examination, quality of life assessment, blood pressure, hematology, biochemistry, total T4, urinalysis, N-terminal pro-B-type natriuretic peptide, and cardiac troponin I at baseline, Day 60, 120, and 180. Fructosamine was analyzed at screening and Day 180. Echocardiograms were performed at all time points excluding Day 120. Outcome variables were compared using Repeated Measures Analysis of Covariance.

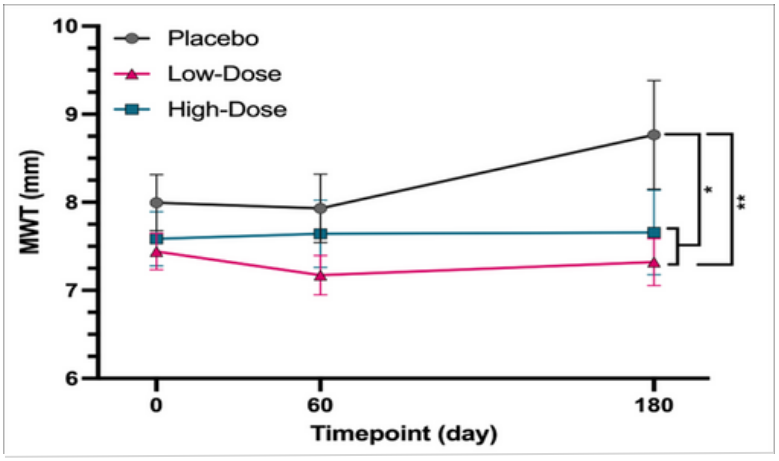

FIGURE 1 ABSOLUTE CHANGE IN MAXIMUM WALL THICKNESS OVER TIME

No demographic, echocardiographic, or clinicopathologic values were significantly different between study groups at baseline confirming successful randomization. At Day 180, the primary study outcome variable, maximum LV myocardial wall thickness at any location, was significantly lower in the low-dose group compared to placebo (p = 0.01). TRIV202 was well tolerated and may reverse or prevent progressive LV hypertrophy in cats with subclinical HCM.

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3. MCMULLEN ET AL. CIRCULATION. 2004;109 (24):3050-77, SHIOI ET AL. CIRCULATION. 2003;107(12):1664-70, VÖLKERS ET AL. CIRCULATION.2013;128 (19)2132-44, WU ET AL. AMERICAN J PATHOL. 2013;182(6):2005-14.
4. RAICHLIN ET AL. TRANSPLANTATION. 2008; 86(10):1395-400