**Title:** Effectiveness of a novel ultra-long acting insulin in dogs with naturally occurring Diabetes Mellitus

**Investigators:**
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**Study description:**
Diabetes mellitus is a relatively common disease in dogs and cats (prevalence of about 0.25-0.50%). Currently, insulin products being used in veterinary medicine must be dosed between one and two times per day, posing a compliance issue for pet owners. In this pilot study, a novel long-acting insulin formulation will be assessed when used as a single injection on a once-weekly basis for the control of hyperglycemia and associated clinical signs.

**Inclusion criteria:**
- Signed owner consent
- Dogs weighing between 3 kg and 50 kg
- Previously diagnosed and treated with insulin at a dose of $\leq 3.0$ U/kg
- Have fair to moderate glycemic control
- Otherwise healthy

**Exclusion criteria:**
- Diabetic ketoacidosis, or history of diabetic ketoacidosis within past 2 months
- Azotemia, elevated bilirubin, or ALT $> 2.5 \times$ upper limit of normal value
- Use of corticosteroids within the past month
- Dogs with concurrent co-morbid illness
- Dogs that are pregnant, lactating or intended for breeding

Duration of enrollment is for a minimum of 3 weeks (4 required visits) or up to 6 weeks (7 required visits). This study will enroll dogs that have been treated for diabetes mellitus with insulin and are considered stable on an insulin dose that is relatively constant from day to day. Dogs will be screened for eligibility based on physical exam, history, and results of routine labwork (complete blood count, chemistry, urinalysis, PLI and fructosamine). If eligible for the study, dogs will return within a week of screening for placement of a FreeStyle Libre Continuous Glucose Monitoring System (CGM) that measures interstitial glucose concentrations continuously up to two weeks at a time. Dogs will return home and continue their current insulin treatment for a week. The following week dogs will return to UGA for repeat labwork and administration of the long-acting insulin. After observation overnight, dogs will return home with the FreeStyle Libre sensor still in place for assessment of glycemic control. Dogs will be assessed each week at UGA to determine control of hyperglycemia and for dose adjustment of the long-acting insulin if owners wish to continue the study. Study enrollment for dogs continuing on long-acting insulin will end after Week 6.

**Study funds will pay for the veterinary consultation and referral visit, labwork required by the study, study rechecks, the continuous glucose monitoring sensors, an AlphaTrack glucometer, and the long acting insulin for the duration of enrollment. In addition, owners**
will receive $1,500 if their dog completes the entire 6-week study. Owners with dogs that complete all four long acting insulin injections are eligible for up to a 1-year supply at a small cost upon renewable mutual consent between owners and the study sponsor, in consultation with the pet’s veterinarian.

**Duration of study:**
This study is currently OPEN.

**Potential benefits to veterinary medicine:**
Data from this study may lead to a new treatment regimen that will allow for less frequent dosing versus standard-of-care insulins, and better overall treatment regimen compliance.