

KU-AS-272, as a Potential Single-Dose Non-hormonal Male and Female Sterilant for Cats and Dogs – *Tash and Roby*

A safe and permanent, easily administered, single-dose non-surgical sterilant in both male and female dogs and cats will reduce the large number of unwanted pets and the burden to pet owners, animal control, and veterinary facilities. KU-AS-272 is a potent single-dose anti-spermatogenic agent that causes sterilization of male rats after a single high dose. KU-AS-272 targets testis Sertoli cells that are critical for spermatogenesis. The ovary contains the same protein targets for KU-AS-272 as well as functionally homologous granulosa cells, critical for oogenesis.

Preliminary data shows that single oral KU-AS-272 administration in female mice reduces ovarian weight and endocrine hormones. Thus, KU-AS-272 is ready to begin non-GLP Phase 1 and 2 trials in male dogs and cats, and detailed proof-of-concept studies in female rats followed by similar trials in female dogs and cats. Our overall goal is to develop KU-AS-272 as a single-dose sterilant in both male and female dogs and cats. Given the mature status of KU-AS-272 in the drug development pathway, we propose to conduct non-GLP FDA style trials through Phase 2. Therefore:

- Objective 1 (Male): Perform KU-AS-272 pharmacokinetic, safety, and efficacy studies in male dogs and cats and conduct non-GLP efficacy trials through Phase 2.
- Objective 2 (Female): Carry out proof-of-concept studies in female rats defining the efficacy of KU-AS-272 as a single-dose sterilant and perform KU-AS-272 PK, safety, and efficacy studies in female cats and dogs and conduct non-GLP efficacy trials through Phase 2.

We will also discuss the overall strategy for carrying KU-AS-272 toward clinical trials. The overall drug development strategy for realizing KU-AS-272 as a single-dose sterilant for male and female cats and dogs will also be discussed.