STEM CELL TREATMENT STUDY FOR CATS WITH CHRONIC KIDNEY DISEASE (CKD)

Hope for cats with a cellular therapeutic targeting the underlying cause.

We need your help!

Do you have feline patients diagnosed with chronic kidney disease (CKD), IRIS grade 2 or greater?

If so, those patients may be eligible for a pivotal study to support FDA-approval of an allogeneic, ready-to-use stem cell therapy for control of their clinical signs associated with CKD.

WHY STEM CELLS:

Stem cells are naturally occurring cells that exist in adult tissues and have regenerative properties (help tissues repair). These stem cells have the ability to immunomodulate (regulation of the immune system to be adaptive) through cellular signaling. This provides a natural and targeted mechanism for treatment of the underlying disease.

The mesenchymal stem cells (MSCs) used in this product are derived from a healthy donor cat's uterus that is collected during a routine spay procedure. The cells are harvested, cultured, expanded, and frozen to provide a source of live cells once thawed at the time of treatment.

There have been multiple studies evaluating adult mesenchymal stem cells in feline patients suffering from CKD.[1-3] Improvements in glomerular filtration rate have been identified in cats following treatment.[3] Several studies have investigated mesenchymal stem cells in other feline diseases; including chronic gingivostomatitis and inflammatory bowel disease.[4-7]

WHY SHOULD YOU AND YOUR CLIENT CONSIDER THIS STUDY?

- Stem cells offer a treatment option for cats with chronic kidney disease.
- Your client's cat will receive specialty veterinary care throughout the study, including physical exams, blood work, and urinalysis at NO OUT-OF-POCKET cost to the pet parent.
- You and your client's cat may play an important role in advancing feline medicine.*

*This study may be used to support a new animal drug application to be submitted to the Food and Drug Administration.

SUMMARY OF STUDY DESIGN:

- Cats must have had a diagnosis of chronic kidney disease prior to enrollment.
- There is a 67% chance that the cats will receive drug. 33% of cats will receive a placebo treatment.
- The stem cell therapy will be administered via intravenous injection via a catheter in the cephalic vein.
- The stem cell therapy consists of an initial treatment followed by a second treatment 14 days apart.
- Cats should not have cancer or other concurrent disease conditions that are not controlled/stable.
- Cats should not have received a stem cell product in the past.

SAFETY SUMMARY:

The study Sponsor has conducted six studies to date that have evaluated the safety of uterine-derived MSCs in cats. The study drug is well tolerated with the overall incidence of adverse events reported across 137 doses administered of 9.5% with 2.2% being considered serious (requiring treatment). The most common observation is vomiting during the administration. There were no hospitalizations or deaths in any cat and all cats recovered uneventfully.

If you are interested in study participation or you have a client that you would like to refer to an active clinical site, please contact Gallant Therapeutics at clinicaltrials@gallant.com.

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Have questions? Email us at info@gallant.com

Interested in participating in the CKD study or have a client you would like to refer to an active site? Scan and email us today.

REFERENCES

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