

# A STEM CELL TREATMENT IS NOW BEING STUDIED IN CATS WITH FELINE CHRONIC GINGIVOSTOMATITIS (FCGS)

Hope for Cats with No Alternative Options



## RISE STUDY

Do you have a cat that has been diagnosed with stomatitis or is showing any of these signs:

- Licking excessively
- Drooling
- Reduced grooming
- Reduced appetite
- Vocalization
- Bleeding gums
- Sores in the mouth

If so, your cat may have Feline Chronic Gingivostomatitis (FCGS), also called gingivostomatitis and caudal stomatitis. The disease causes painful lesions in your cat's mouth that markedly impacts their quality of life and wellbeing. If your cat has already undergone medical treatment and extraction of their teeth and are still showing clinical signs of disease and lesions in the mouth they are considered refractory and have limited to no currently available treatment options.

## WHY STEM CELLS

Stem cells are naturally occurring cells that exist in adult tissues and have regenerative properties (help tissues repair and heal). They have the ability to modify the immune system and target the underlying disease process.

The stem cells used in this product are derived from a healthy donor cat's uterus that is collected during a routine spay procedure. Rather than the uterus being discarded as normal after surgery, it is packaged in a sterile manner and shipped to the manufacturing facility. The donor cat recovery follows a normal spay procedure.

The mesenchymal stem cells are harvested, cultured, expanded, and frozen at ultra cold temperatures to provide a source of live cells once thawed at the time of treatment. 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 disease.

## WHY SHOULD MY CAT BE CONSIDERED FOR THIS STUDY?

- ✓ Your cat will receive specialty veterinary care throughout the study, including physical exams, blood work, and urinalysis at NO OUT-OF-POCKET cost to you.
- ✓ Your 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.*

## YOUR RESPONSIBILITIES

- Consenting to your cat participating in all study procedures
- Bringing your cat to all the in-clinic visits
- Following the protocol regarding medications that can or cannot be used during the study
- Performing any required owner assessments including a daily diary of health and behavior observations
- Notifying the study veterinarian if there any abnormal signs your cat is experiencing during the study

## SAFETY

- The potential risks are described in the informed owner consent that you will be asked to read and sign prior to your cat being enrolled
- The study veterinarian will review the owner informed consent with you prior to screening and will answer any questions you may have

## SUMMARY OF STUDY PROCEDURES

- There is a 100% chance that your cat will receive drug. Cats serve as their own control and there is no placebo group.
- Your cat will be assessed for enrollment based on evidence of FCGS, a minimum lesion score, and a minimum owner specific outcome score.
- Your cat must have undergone partial or full-mouth extractions.
- Your cat must have been on medical therapy in addition to extractions.
- The cell therapy will be administered in a vein (intravenously) through a catheter in your cat's leg, similar to how fluids are normally administered when they are in the hospital
- Cats should not have cancer or other concurrent disease conditions that are not controlled/stable.
- The cell therapy consists of two treatments, 14 days apart.

## QUESTIONS?

Email us at [info@gallant.com](mailto:info@gallant.com)



Interested in participating in the FCGS study?  
**Scan and email us today.**