



# STEM CELL TREATMENT STUDY FOR CATS WITH REFRACTORY FELINE GINGIVOSTOMATITIS

Targeting the root cause

**We need your help!** Do you have feline patients diagnosed with chronic gingivostomatitis (FCGS) based on Stomatitis Disease Activity Index (SDAI) lesion scoring and clinical signs including:

- Licking excessively
- Drooling
- Reduced grooming
- Inappetence
- Weight loss
- Halitosis
- Vocalization
- Bleeding gums
- Ulcers in the mouth

If so, those patients may be eligible for a pivotal study to support FDA-approval of an allogeneic, ready-to-use stem cell therapy.

## WHY STEM CELLS

Mesenchymal stem cells (MSCs) are naturally occurring cells that exist in adult tissues and have regenerative properties (help tissues repair and heal). MSCs have the ability to immunomodulate (regulation of the immune system) through cellular signaling. This provides a natural and targeted mechanism of action directed at the underlying disease pathogenesis.

The 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 demonstrating the ability of adult mesenchymal stem cells to improve lesions scores and, more importantly, clinical status of feline patients suffering from refractory FCGS.<sup>1-4</sup>

## WHY SHOULD YOU AND YOUR CLIENT CONSIDER THIS STUDY?

- ✓ MSCs offer a solution for cats that have not responded to tooth extraction and medical management.
- ✓ 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.

**RISE  
STUDY**

## SUMMARY OF STUDY DESIGN

- Cats must have had full mouth extraction at least 60 days prior to enrollment.
- There is a 100% chance that the cats will receive drug. Cats serve as their own control and there is no placebo group.
- Cats may continue their current medical therapy.
- Treatment will be a single injection administered via a catheter on an outpatient basis.
- The cell therapy consists of two treatments, 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. The most common observations during treatment include nausea/vomiting and increased respiratory rate in a small percentage of cats. There have been no hospitalizations or deaths related to injection of the product and all cats have 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](mailto:clinicaltrials@gallant.com).

## QUESTIONS?

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



Interested in participating in the FCGS study or  
have a client you would like to refer to an active site?

**Scan and email us today.**

1. Arzi B, Mills-Ko E, Verstraete FJM, et al. Therapeutic Efficacy of Fresh, Autologous Mesenchymal Stem Cells for Severe Refractory Gingivostomatitis in Cats. *Stem Cells Transl Med.* 2016 Jan 1;5(1):75–86.
2. Arzi B, Clark KC, Sundaram A, et al. Therapeutic Efficacy of Fresh, Allogeneic Mesenchymal Stem Cells for Severe Refractory Feline Chronic Gingivostomatitis. *Stem Cells Transl Med.* 2017/06/15 ed. 2017 Aug;6(8):1710–22.
3. Taechangam N, Williams V, Hughes M, et al. Pilot Efficacy of Allogeneic Uterine-Derived Mesenchymal Stem Cells for the Treatment of Refractory Feline Chronic Gingivostomatitis. *N Amer Vet Reg Med Assoc abstract* 2023.
4. Data on File (FS-001, FS-002, FS-003). Gallant Therapeutics 2021-2024.