Tirasemtiv in ALS: A phase 3 double-blind placebo-controlled study. Cytokinetics is sponsoring a study of this investigational oral agent to see its effect on breathing and limb muscle strength. For more information go to [link to clinicaltrials.gov].

All participants will take active drug for two weeks. Participants that cannot tolerate the drug will not be allowed to continue participation in the study. Participants that tolerate the drug well will be randomized to one of four groups: high dose, medium dose, low dose and placebo (sugar pill.) The entire study includes at least 16 visits to Emory over 56 weeks. If side effects occur, additional visits to Emory will be required.

This medication changes the way that Riluzole is used in the body. Both people who take riluzole and those that don’t take it will be considered however there will be some changes in the way riluzole is dosed for people already on Riluzole. People who do not take riluzole cannot start it after they begin participation in this study.

Some of the key criteria for the study enrollment are:

- Duration of illness of less than or equal to 24 months from diagnosis
- Vital capacity of at least 70%
- Ability to swallow tablets at screening and expected to be able to swallow tablets for the duration of the study.
- No use of NIPPV or oxygen
- No diaphragm pacing system and no plans to get one
- Taking tizanidine and/or theophylline containing medications and unwilling or unable to stop
- Other neurologic illnesses in addition to ALS
- Significant medical illnesses
- Prior stem cell therapy of any form
- Previous use of tirasemtiv