FIGHT



Trial name. **TECFIDERA**

WHY TECFIDERA MAY HELP MND PATIENTS

The term neuroinflammation describes the triggering of the immune system within the central nervous system (brain and spinal cord). Neuroinflammation is considered to play a very important role in how fast a person with MND's disease progresses. While some immune cells are considered harmful and contribute to the death of the motor neurons, other immune cells, such as the T-regulatory cells (Tregs), are thought to be protective and may help slow the disease down.

TECFIDERA

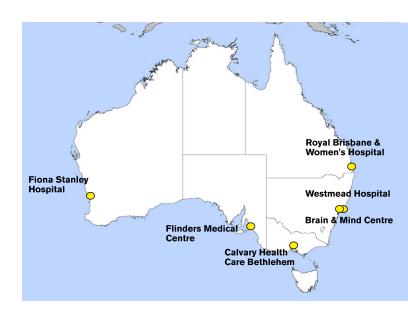
The drug, Tecfidera, is a clinically approved drug that is used to treat relapsing multiple sclerosis (MS). It works by reducing neuroinflammation and importantly, Tecfidera has been shown to increase the levels of Tregs in humans. Researchers hope that by administering Tecfidera to MND patients, they will be able to increase the levels of the protective Tregs and slow down the progression of disease.

THE EVIDENCE FOR THIS **INCLUDES:**

- In MND patients, lower Treg numbers have been linked to a faster progression of disease.
- In MND patients, higher Treg numbers have been linked to a slower progression of disease.
- MND mice that were given drugs to increase Treg numbers had a slower progressing disease and lived longer than MND mice who didn't receive treatment.



Trial name. TECFIDERA



MOVING FROM THE LABORATORY INTO THE CLINIC

This will be the first clinical trial in the world to test Tecfidera in patients with MND/ALS. The trial began recruiting in April 2018 will be run at 6 trial sites across Australia:

Tecfidera trial sites

- Brain and Mind Centre, Sydney
- Westmead MND Clinic, Sydney
- Calvary Health Care Bethlehem, Melbourne
- Royal Brisbane & Women's Hospital, Brisbane
- Flinders Medical Centre, Adelaide
- Fiona Stanley Hospital, Perth.

For full details on the study protocol visit

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx.ACTRN=12618000534280

STUDIES ON TREGS IN MND/ALS

- Henkel JS et al., (2013) Regulatory
 T-lymphocytes mediate amyotrophic lateral sclerosis progression and survival. EMBO
 Mol Med. 2013 Jan,5(1).64-79
- 2. Beers DR et el., (2010) Endogenous regulatory T lymphocytes ameliorate amyotrophic lateral sclerosis in mice and correlate with disease progression in patients with amyotrophic lateral sclerosis. Brain. 2011 May,134(Pt 5).1293-314 Sheean RK et al., (2018) Association of Regulatory T-Cell Expansion With Progression of Amyotrophic Lateral Sclerosis. A Study of Humans and a Transgenic Mouse Model. JAMA Neurol. Published online March 5 doi.10.1001/jamaneurol.2018.0035