The FDA approval of RADICAVA ORS is supported by several clinical trials evaluating the oral and IV formulations of edaravone.

RADICAVA ORS is an oral form of edaravone, the active ingredient in RADICAVA, an FDA-approved IV treatment for ALS that has been shown to slow the loss of physical function by 33% (approximately one-third) vs. placebo, as measured by the ALSFRS-R.[1,3] Specifically, a Phase 3 clinical trial (Study MCI186-19) evaluating 137 people with ALS was conducted with RADICAVA versus placebo. That study demonstrated that at 24 weeks (about 6 months), study participants who did not receive RADICAVA declined more rapidly in physical function, having lost an average of 2.49 points more than those who received RADICAVA.[1,3] The most common adverse events that occurred in greater than 10 percent of people treated with RADICAVA were bruising (contusion), problems walking (gait disturbance) and headache.[1,3] Since 1995, RADICAVA is the only FDA-approved treatment for ALS with positive results from a Phase 3 trial despite more than 125 clinical trials from 2008-2019.[1,3,5]

In addition, RADICAVA ORS was evaluated across seven Phase 1 clinical trials, as well as a global Phase 3, 24-week trial demonstrating the safety and tolerability profile of the treatment in 185 people with ALS.[1,6] Fatigue was observed in 7.6% of patients taking RADICAVA ORS.[1,6]

What were the safety results?

RADICAVA ORS offers people with ALS a similar safety profile as RADICAVA, the IV formulation. In a clinical trial for RADICAVA the most common adverse events that occurred in greater than 10% of people treated with RADICAVA were bruising (contusion), problems walking (gait disturbance) and headache.[1,3]

The safety and tolerability of RADICAVA ORS was demonstrated in a global Phase 3 trial evaluating 185 people with ALS for 24 weeks (about 6 months).[1,6] Fatigue was observed in 7.6% of study participants.[1,6] Fewer than 6% of people discontinued RADICAVA ORS due to study side effects.[1,6] Approximately 1% of people discontinued RADICAVA ORS due to gastrointestinal side effects (diarrhea and trouble swallowing).[1,6] Other reasons for discontinuation (1%) included respiratory failure and muscular weakness.[1,6]

RADICAVA and RADICAVA ORS may cause serious side effects. These include:

Hypersensitivity (allergic) reactions: Hypersensitivity reactions have happened in people receiving RADICAVA and can happen after your infusion is finished.

Sulfite allergic reactions: RADICAVA and RADICAVA ORS contains sodium bisulfite, a sulfite that may cause a type of allergic reaction that can be serious and life-threatening. Sodium