CHAMPION ALS 308

CHANGING PARADIGMS IN COMPLEMENT INHIBITION

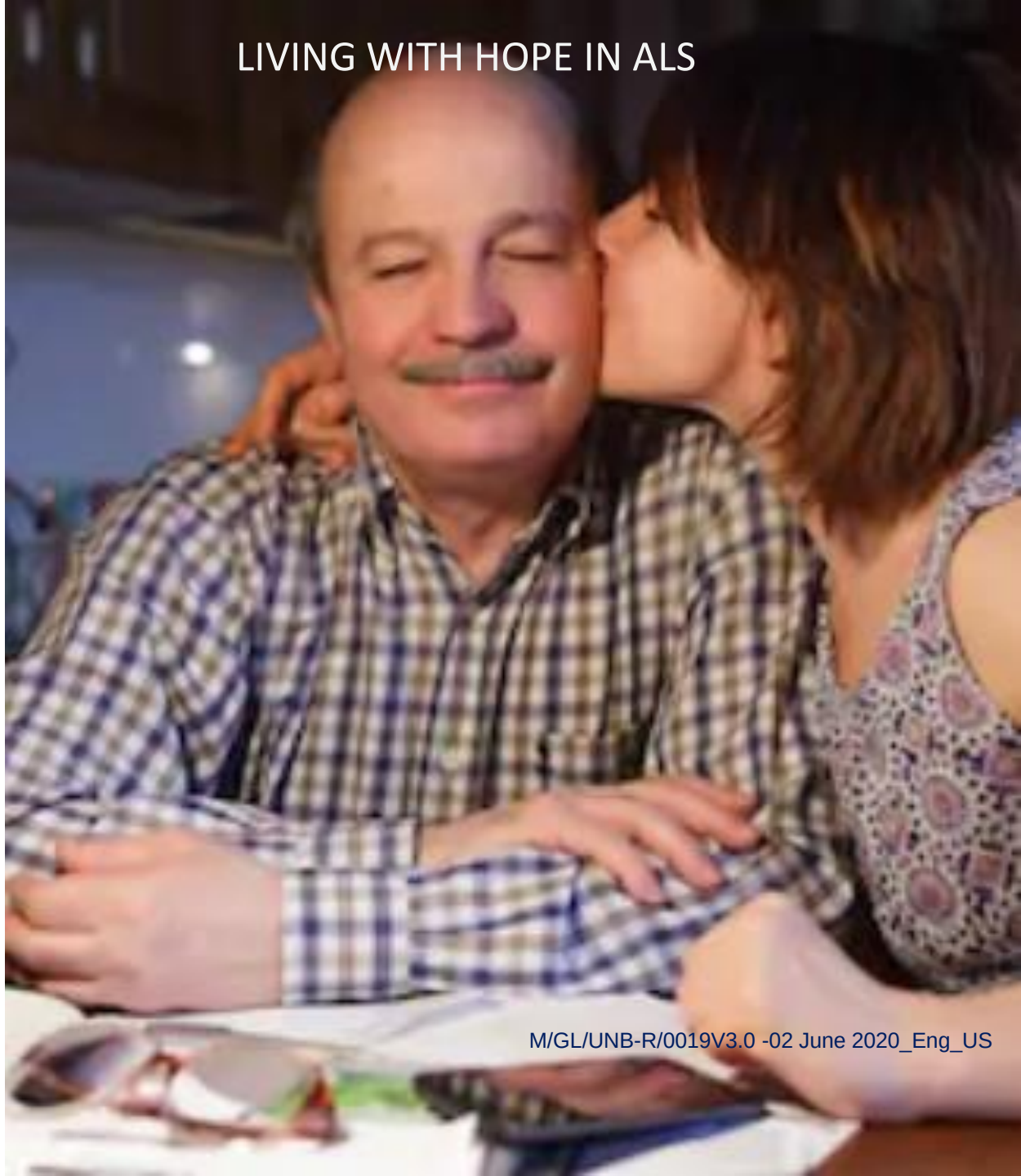
Study Overview

CLINICAL STUDY IN

AMYOTROPHIC LATERAL SCLEROSIS (ALS)

Ravulizumab-cwvz is not currently FDA-approved for the treatment of ALS.

ALEXION®



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ALEXION IS SINGULARLY DEDICATED TO RARE DISEASE

EVERY DAY IS AN INSPIRATION

People living with rare and devastating diseases are our inspiration and our Guiding Star.

Our mission is to transform the lives of people affected by rare and devastating diseases, by continuously innovating and creating meaningful value in all that we do.

We believe it is our responsibility to listen to, understand, and change the lives of patients and those who work tirelessly to help them.

Source: https://alexion.com/our-company/about-us. Updated January28, 2020. Accessed February 2020.

A commitment to breakthrough innovation

Alexion was established in 1992 and is focused on developing life-changing therapies for patients with severe and potentially life-threatening rare diseases.

About Alexion: Our History https://alexion.com/about-alexion-pharmaceuticals/history. Updated January 2020. Accessed February 2020.

WHAT IS ALS?

Amyotrophic lateral sclerosis (ALS) is a rare neurological disorder of progressive deterioration of nerve cells (motor neurons) in the brain and the spinal cord that control muscles throughout the body.

When the nerve cells die, the brain can no longer control muscle movement, and people with ALS may lose the ability to speak, eat, move and breathe.

As ALS progresses, the upper and lower motor neurons deteriorate in 4 areas of muscle function, causing severe disability:

Bulbar (mouth and throat)

- Abnormal speech or inability to speak
- Difficulty chewing and swallowing

Gross motor (upper and lower limbs)

- Difficulty walking or climbing stairs
- Muscle cramps and pain
- Paralysis

Fine motor (hands and fingers)

- Difficulty writing or holding a pen
- Trouble cutting food or using utensils
- Unable or needs support with hygiene and self-care

Respiratory (chest)

- Difficulty breathing
- Weak cough
- Respiratory distress

Sources: 1. NIH Fact Sheet on ALS. https://www.ninds.nih.gov/disorders/patient-caregiver-education/fact-sheets/amyotrophic-lateral-sclerosis-als NIH. **2.** The ALS CNTF Treatment Study (ACTS) Phase I-II Study Group, *Arch Neurol*. 1996;53:141-147. **3.** Cedarbaum JM et al. *Journal of the Neurological Sciences* 169 (1999) 13–21 . **4**. Hardiman, O.,et al. *Nat Rev Dis Primers* 3, 17071 (2017). https://doi.org/10.1038/nrdp.2017.71

The causes of ALS are largely unknown, but inflammation may play a role. Complement is a part of the immune system and helps your body fight infections.

Overactive complement may play a role in ALS through damage to the motor neurons and the activation of inflammation.

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Source: Parker SE, et al. *Neurobiology of Disease* 2019; (127) 223–232.

STUDY DESCRIPTION

The CHAMPION ALS study is a Phase 3 study to assess the safety and efficacy of the experimental drug, ravulizumab-cwvz, and is planning to enroll 354 people with ALS in 120 study centers worldwide

For a list of study locations, please visit https://ALSCHAMPION.com or www.clinicaltrials.gov/ct2/show/NCT04248465.

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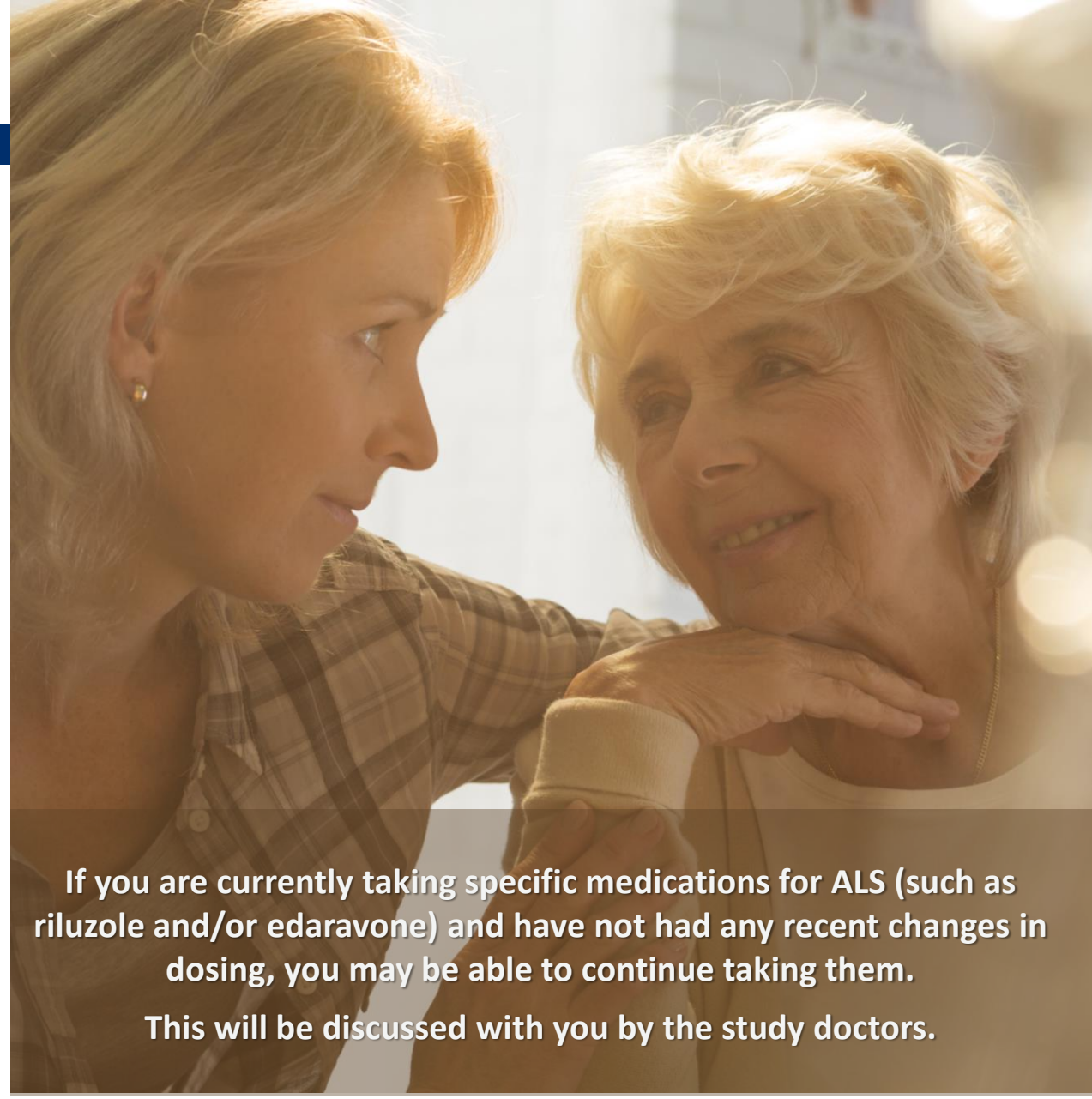
Source: Data on file, Alexion Pharmaceuticals, Inc.

You may be eligible to participate in this study if you are an adult, 18 years of age or older and:

- ✓ Have been diagnosed with ALS
- ✓ The first signs and symptoms of motor weakness (such as abnormal speech, difficulty swallowing, shortness of breath and limb weakness) has occurred within the past 36 months
- ✓ Your breathing ability meets the study criteria and you are not dependent on a ventilator or other respiratory support
- ✓ You have been vaccinated against *N. meningitidis* in the past 3 years or are willing to be vaccinated to participate in the study
- ✓ Have not been treated with a complement inhibitor



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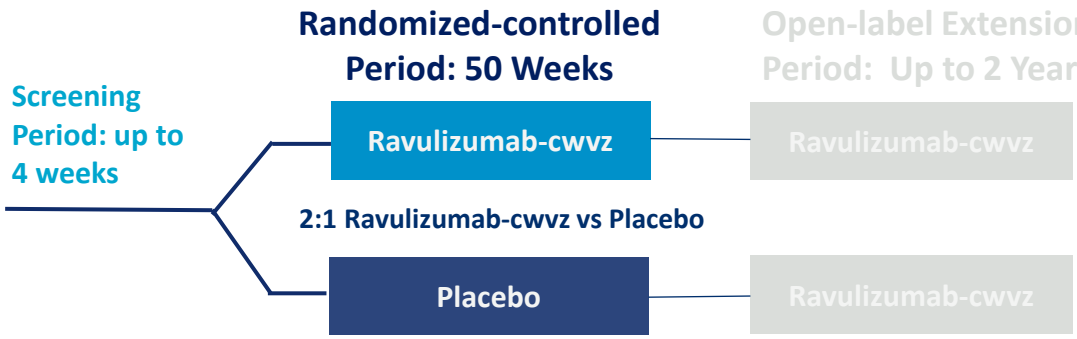
Source: Data on file, Alexion Pharmaceuticals, Inc.

During the Randomized-controlled Period, you will be given the study medication, either ravulizumab-cwvz or placebo (an inactive substance) by intravenous infusion (IV) for a total of 50 weeks

- Neither you nor the study coordinators, physicians or nursing staff will know whether you have been given ravulizumab-cwvz or placebo
- 2 weeks after the initial dose, you will receive the study medication once every 8 weeks



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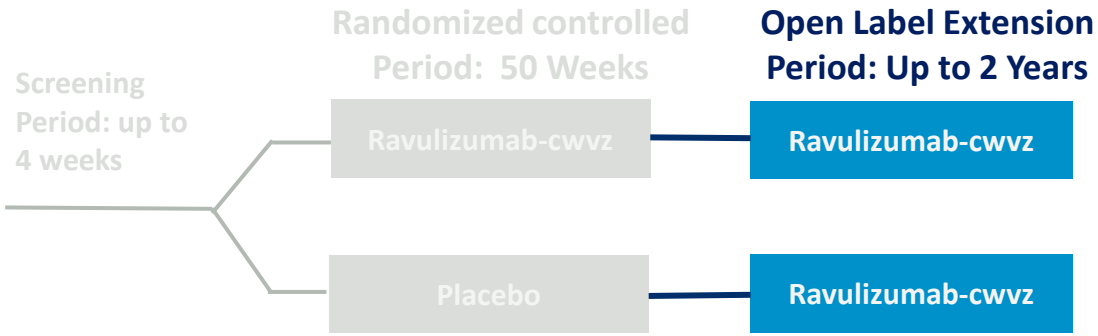
Source: Data on file, Alexion Pharmaceuticals, Inc.

After 50 weeks on the study medication, you will have the opportunity to participate in the Open-label Extension Period

- In this period, every participant will be given ravulizumab-cwvz, even if they had previously received placebo
- The Open-label Extension Period will last up to 2 years



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Source: Data on file, Alexion Pharmaceuticals, Inc.

IN SUMMARY

- **Phase 3 study** in Amyotrophic Lateral Sclerosis (ALS) is now enrolling
- **2:1 ravulizumab-cwvz vs placebo** during the Randomized-controlled Period
- **All study participants will have the opportunity to receive ravulizumab-cwvz** during the Open-label Extension Period, including participants who received placebo in the previous period
- **You may be able to stay on your current treatments for ALS** as long as they meet the study requirements
- **Study medication, travel expenses and visit assessments will be provided at no cost** to you by the sponsor (Alexion)

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Source: Data on file, Alexion Pharmaceuticals, Inc.

To learn more about the CHAMPION ALS Study go to ALSChampion.com

or contact Alexion at: info@championscreening.com

TALK TO YOUR DOCTOR or go to https://clinicaltrials.gov/ct2/show/NCT04248465

if you are interested in learning more about participating in the CHAMPION ALS Study

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