Radicava (Edaravone) Findings in Biomarkers From ALS (REFINE-ALS)

Dear Potential Study Participant,

We invite you to learn more and consider participation in the REFINE-ALS study.

The REFINE-ALS study (Radicava® (edaravone) Findings in Biomarkers from ALS) is being conducted by the Northeast Amyotrophic Lateral Sclerosis Consortium (NEALS), and Mitsubishi Tanabe Pharma America (MTPA) as the sponsor. The study is approximately 24 weeks long and being conducted at approximately 40 Amyotrophic Lateral Sclerosis Consortium clinics across the United States and Canada.

Radicava®, manufactured by MTPA, is an FDA-approved prescription drug shown in a clinical trial to slow ALS progression. In this study, we aim to study people with Amyotrophic Lateral Sclerosis (ALS) who are taking IV or oral Radicava® and perform blood and urine analyses for measurable indicators of change called biomarkers. Our goal is to learn more about the biology of ALS, disease progression, and the possible treatment effect of Radicava® by studying these biomarkers.

You may be eligible for this study if you have been diagnosed with ALS, and you have not yet started IV or oral Radicava, but have decided to start it, in conjunction with your physician. If you do participate in the study, you will obtain IV or oral Radicava® through your current medical and pharmacy coverage plan (i.e. Medicare, HMO, PPO, etc.).

Your decision to participate in this study is voluntary, and this letter is for informational purposes only. Please discuss all available treatment options with your physician. Whether or not you decide to participate in this study, your decision will not restrict your access to Radicava® treatment.

If you are interested in learning more about this study, please review the list of study centers on the following pages. You do not have to respond if you are not interested in this study. You may receive this letter again as a follow-up in the mail, which you can simply disregard.

Thank you for your time and consideration. We look forward to hearing from you.

Dr. James Berry, MD
Massachusetts General Hospital
REFINE-ALS Principal Investigator

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Site Name	PI Name	Primary Coordinator (Name, Email Address, Phone number)
Massachusetts General Hospital	Suma Babu, MD, MPH	Mackenzie Keegan 617-643-6252 mkeegan@mgh.harvard.edu
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UC Davis Health	Nanette Joyce, DO	Aubrey Hanshaw 916-734-5057 anhanshaw@ucdavis.edu
Saint Louis University Department of Neurology	Ghazala Hayat, MD	Dr. Ghazala Hayat ghazala.hayat@health.slu.edu
Medical College of Wisconsin	Dominic Fee, MD	Marie Mejaki 414-955-0667 mmejaki@mcw.edu
Medical University of South Carolina	Amy Chen, MD, Ph.D	Emily Richardson 843-792-8352 richaemi@musc.edu
University of Florida, Jacksonville - Neurology Research Department	Michael Pulley, MD, Ph.D	Yasmeen Shabbir Yasmeen.Shabbir@jax.ufl.edu
Neurology Associates, P.C.	Gary Pattee, MD	Wendy Bradford 402-770-7403 wendy@somnos.com
John Hopkins University	Nicholas Maragakis, MD	Betsy Mosmiller 410-502-0495 emosmil1@jhmi.edu
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