QurAlis Doses First Participant Cohort in Phase 1 Multiple-Ascending Dose (MAD) Clinical Trial Evaluating QRL-101, a First-in-Class Kv7 Precision Therapy for ALS

QRL-101 aims to reduce hyperexcitability-induced neurodegeneration, which is present in approximately 50 percent of all ALS patients

Completed Phase 1 single-ascending dose (SAD) clinical trial of QRL-101 enrolled 88 participants; no reported significant safety concerns or serious adverse events

MAD data expected to be reported in first half of 2025; results will support larger global studies in people living with ALS

CAMBRIDGE, Mass., *September 10, 2024* – QurAlis Corporation ("QurAlis"), a clinical-stage biotechnology company driving scientific breakthroughs into powerful precision medicines that have the potential to alter the trajectory of amyotrophic lateral sclerosis (ALS), frontotemporal dementia (FTD), and other neurodegenerative and neurological diseases, today announced that the company recently completed dosing of the first participant cohort in the Phase 1 multiple-ascending dose (MAD) clinical trial evaluating QRL-101 (QRL-101-03; NCT06532396). QRL-101 is a first-in-class selective Kv7.2/7.3 ion channel opener for the treatment of hyperexcitability-induced disease progression in ALS. Kv7.2 is a mis-spliced protein in sporadic ALS patients.

QRL-101-03 is a randomized, double-blind, placebo-controlled, single-site Phase 1 clinical trial designed to evaluate the safety, tolerability, and pharmacokinetics of multiple-ascending doses of QRL-101 in adult healthy volunteers. The study is expected to enroll approximately 60 participants, who will be randomized in a 9:3 ratio of QRL-101 to placebo into five planned cohorts. The dose range of QRL-101 for this MAD study was determined by results from QurAlis' Phase 1 single-ascending dose (SAD) clinical trial (QRL-101-01; NCT05667779). Of the 88 healthy participants in the SAD clinical trial, no significant safety concerns or serious adverse events have been reported for QRL-101.

"We are excited to complete dosing of our first participant cohort in our Phase 1 MAD clinical trial of QRL-101. In the SAD study, QRL-101 was shown to be well tolerated, with no significant safety concerns or serious adverse events," said Doug Williamson, M.D., chief medical officer of QurAlis. "ALS is a devastating, fatal neurodegenerative disease and there are currently no therapies that can significantly extend patients' lives. QRL-101 has the potential to be a first-in-class effective therapy for ALS patients suffering from hyperexcitability-induced motor neuron degeneration. We look forward to advancing the clinical program for QRL-101 so QurAlis can bring much-needed therapies to people living with ALS."

"Motor system hyperexcitability occurs in approximately 50 percent of all ALS patients and is linked to potassium channel dysfunction," said Leonard H. van den Berg, M.D., Ph.D., professor of neurology and chair, TRICALS. "QRL-101, is a highly selective Kv7.2/7.3 ion channel opener, which in preclinical models shows a strong potential to control motor neuron hyperexcitability-induced neurodegeneration with an attractive side effect profile. We are encouraged by the findings from the SAD study of QRL-101 and look forward to results from the MAD study."

QurAlis anticipates reporting topline data from the Phase 1 MAD clinical trial of QRL-101 in the first half of 2025.

More information about the QRL-101 Phase 1 clinical trials can be found at www.clinicaltrials.gov.

About Amyotrophic Lateral Sclerosis (ALS)

Amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease, is a progressive neurodegenerative disease impacting nerve cells in the brain and spinal cord, reducing muscle function and control. ALS can be traced to mutations in more than 25 different genes and is often caused by a combination of multiple sub-forms of the condition. Cases usually cannot be predicted, although a small percentage are inherited. ALS has a devastating impact on patients and families. ALS patients' average life expectancy is three years; after diagnosis patients only have two years to live. There is currently no cure for the disease.

About Kv7

Kv7.2/7.3 is a voltage-gated potassium channel whose role is crucial for the regulation of neuronal excitability and membrane potential. Kv7.2 is mis-spliced in sporadic ALS leading to loss of function and abnormal electrical activity in the spinal cord and brain. The activation of this channel shows the potential to decrease spinal and cortical/motor neuron excitability and to positively affect CMAP (compound muscle action potential). This suggests that this may be an effective therapeutic approach for ALS patients suffering from hyperexcitability-induced motor neuron degeneration.

About QurAlis Corporation

At QurAlis, we are neuro pioneers on a quest to cure. We work with a relentless pursuit of knowledge, a precise attention to craft, and an optimistic mindset to discover and develop effective precision medicines that have the potential to alter the trajectory of amyotrophic lateral sclerosis (ALS), frontotemporal dementia (FTD), and other neurodegenerative and neurological diseases. Founded by an internationally recognized team of neurodegenerative biologists from Harvard Medical School and Harvard University, QurAlis is advancing a robust precision medicine pipeline with therapeutic candidates aimed at modifying severe disease pathology in defined patient populations based on both disease-causing genetic mutation(s) and clinical biomarkers. For more information, please visit www.quralis.com or follow us on X @QurAlisCo or LinkedIn.

Contact:

Kathy Vincent
kathy.vincent@quralis.com
310-403-8951

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