

QurAlis and Unlearn Announce Collaboration to Accelerate and Optimize ALS Clinical Trials With Generative Artificial Intelligence Technologies

Collaboration will leverage Unlearn's AI-powered digital twins in QurAlis' clinical trials for their leading ALS therapies

CAMBRIDGE, Mass., and SAN FRANCISCO – June 27, 2023 – [QurAlis Corporation](#), a clinical-stage biotechnology company developing breakthrough precision medicines for amyotrophic lateral sclerosis (ALS) and other neurodegenerative diseases with genetically validated targets, and [Unlearn](#), a pioneering technology company innovating machine learning to revolutionize medical research, today announced they have entered into a collaboration to accelerate and optimize QurAlis' clinical program in ALS with Unlearn's advanced generative artificial intelligence (AI) technology.

Unlearn develops digital twins of clinical trial patients that are predictions of individual health outcomes under the control treatment over time. Digital twins are employed in randomized controlled trials (RCTs) called TwinRCTs to run more efficient trials that [produce regulatory-suitable evidence](#).

“Advances in machine learning and AI make it possible to enhance trial power to detect a positive result when one truly exists while controlling for Type-1 error and significantly shorten timelines without introducing bias into the study,” said Kasper Roet, Ph.D., founder and chief executive officer (CEO) of QurAlis. “We are excited to partner with Unlearn to help advance our clinical program with AI and other innovative technologies to generate evidence suitable for supporting regulatory decisions and help speed new, lifesaving precision medicines to patients with ALS and other neurodegenerative diseases.”

The collaboration aims to reduce variability and increase the study power in QurAlis' clinical trials for QRL-201 and QRL-101, the Company's lead product candidates in ALS. Unlearn's patented machine learning models are trained on existing clinical data. After validation, they are used to generate digital twins from baseline data for each patient enrolled in a TwinRCT, regardless of their randomization assignment. Prognostic scores derived from digital twins are incorporated into the trial's primary analysis to precisely estimate treatment effects and control for Type-1 error.

“By using machine learning to leverage the wealth of existing patient data from completed clinical trials, our technology significantly shortens typical timelines by months while generating evidence suitable for supporting regulatory decisions,” said Charles Fisher, Ph.D., founder and CEO of Unlearn. “The AI technology we're developing today will revolutionize the future of clinical research.”

QRL-201 is a first-in-class therapeutic product candidate aiming to restore STATHMIN-2 (STMN2) expression in ALS patients. STATHMIN-2 is a well-validated protein important for neural repair and axonal stability, the expression of which is significantly decreased in nearly all ALS patients. QRL-201 rescues STMN2 loss of function in QurAlis ALS patient-derived motor neuron disease models in the presence of TDP-43 pathology. QRL-201 recently entered the clinic in the first-ever clinical trial to evaluate a therapy that rescues STMN2 in people with ALS (ANQR; NCT05633459).

QRL-201 is the second program in QurAlis' pipeline to enter the clinic recently. In December 2022, QurAlis announced the Company initiated dosing of QRL-101 in a first-in-human Phase 1 clinical trial (NCT05667779). 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.

About QurAlis Corporation

QurAlis is trailblazing the path to conquering amyotrophic lateral sclerosis (ALS) and other neurodegenerative diseases with genetically validated targets with next-generation precision medicines. QurAlis' proprietary platforms and unique biomarkers enable the design and development of drugs that act directly on disease-causing genetic alterations. Founded by an internationally recognized team of neurodegenerative biologists from Harvard Medical School and Harvard University, QurAlis is advancing a deep pipeline of antisense oligonucleotides and small molecule programs including addressing sub-forms of ALS that account for the majority of ALS patients. For more information, please visit www.quralis.com or follow us on Twitter @QurAlisCo.

About Unlearn

Unlearn is a San Francisco-based technology company pioneering AI-generated digital twins that forecast health outcomes for individual patients. Founded in 2017, Unlearn brings together a team of world-class innovators at the intersection of artificial intelligence, clinical, and regulatory science to transform the future of medicine through generative AI. Unlearn's technology is regulatory-qualified and used by leading global pharmaceutical companies to run AI-powered clinical trials that reach full enrollment faster and bring new treatments to patients sooner. For more information, please visit <https://www.unlearn.ai> or follow @UnlearnAI on Twitter, @unlearn-ai on LinkedIn.

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