



Montara Therapeutics Announces Development Candidate for First BrainOnly™-Enabled Program in TSC-Related Epilepsy and Appoints Chief Business Officer

- Montara's BrainOnly platform is designed to prevent peripheral side effects and concentrate neurological drugs' activity in the brain via two-drug combination therapies, comprising its non-brain-penetrant "universal" peripheral blocker development candidate, MT1110, and a brain-penetrant target-specific drug
- Montara will enter the clinic in H2 2026 to study an MT1110-everolimus combination, called MTX-E1, for the treatment of TSC-related epilepsy and other mTOR-driven CNS diseases
- Montara, in collaboration with TSC Alliance and Psychogenics, presents initial preclinical data on the MT1110-everolimus combination at the AES Annual Meeting
- Jeremy Grunstein, PhD, MBA, joins Montara as Chief Business Officer to lead the company's strategic efforts to combine MT1110 with existing and investigational CNS disease-targeted drugs

SAN FRANCISCO, December 8, 2025 – Montara Therapeutics, a preclinical stage biotechnology company pioneering brain-selective therapies for central nervous system (CNS) diseases, today announces the naming of its first development candidate for the BrainOnly platform. The technology enables brain-selective pharmacology of small-molecule CNS drugs by pairing them with a universal, peripherally restricted blocker in a two-drug combination. The universal blocker development candidate, MT1110, saturates FKBP12 binding sites in the periphery, preventing FKBP12-dependent drugs from binding their targets outside of the brain. As a result, the platform has the potential to unlock targets previously considered undruggable due to peripheral side effects or toxicities, greatly expanding therapeutic options for patients.

"The nomination of this development candidate marks a major milestone for Montara, less than two years after beginning operations," said Nicholas T. Hertz, PhD, Founder and CEO of Montara. "It demonstrates our potential to safely saturate FKBP12 binding sites outside the brain to effectively block peripheral drug activity. We are on track to initiate clinical studies in H2 2026 to evaluate the safety and pharmacology of MT1110

as a single agent and in combination with everolimus to treat TSC-induced epilepsy and other mTOR-driven CNS diseases.”

In preclinical studies, MT1110 resolves on-target, off-tissue peripheral side effects that currently limit the safety and efficacy of everolimus, the current standard of care for tuberous sclerosis complex (TSC)-related seizures, to treat patients suffering from this disease. The peripheral blocker MT1110 works with naturally FKBP12-dependent drugs, such as everolimus, as well as with novel bifunctional Brain Targeting Chimeric (BrainTAC™) drugs, engineered by Montara to confer FKBP12 dependence, leveraging Montara’s proprietary know-how in molecular engineering and precision pharmacology.

The company’s lead program, MTX-E1, combines MT1110 with everolimus to treat TSC-associated epilepsy, a disease caused by the hyperactivation of the mTOR pathway. Recent data, presented in collaboration with the TSC Alliance and Psychogenics at the American Epilepsy Society (AES) Annual Meeting, highlighted the superiority of the MT1110-everolimus combination in controlling seizures in a conditional *Tsc1* knockout model, compared to an equivalent dose of everolimus alone. Reduction in everolimus-driven adverse events in the mice co-dosed with MT1110 was also reported in the same study. As highlighted by this collaboration, Montara is working closely with the TSC Alliance to advance the lead program, leveraging their extensive research expertise and proprietary *in vivo* models.

“We’ve enjoyed a productive collaboration with the Montara team as they advance their MT1110-everolimus combination program into clinical testing for this grievous unmet need,” said Dean Aguiar, PhD, Vice President of Translational Research at the TSC Alliance.

Montara is also building an R&D pipeline around the BrainOnly platform and previously announced a collaboration with the Michael J. Fox Foundation on a two-drug combination of MT1110 with a novel LRRK2-targeting BrainTAC.

The company has also appointed Jeremy Grunstein, PhD, MBA, as Chief Business Officer, overseeing all business and corporate development activities.

“I’m excited to join Montara to help translate the growing interest in the BrainOnly™ platform into strategic partnerships, as we work to address the significant and urgent unmet needs of patients impacted by a spectrum of CNS diseases,” said Dr. Grunstein.

Montara CEO Dr. Hertz added, “We’re delighted to welcome Jeremy, who brings extensive experience leading business development and transactions on both the buy and sell side at large and midsize public companies, to Montara at a critical science juncture.”

Dr. Grunstein most recently served as Senior Vice President of Business Development at Xencor (2019–2025), where he executed more than 25 strategic transactions, including collaborations, out-licenses, spin-outs, and royalty monetizations. Previously, during his 16 years at Amgen, he led key acquisitions and in-licensing initiatives that advanced multiple phase 3 and approved programs across therapeutic areas. Dr. Grunstein holds a PhD in Biology from the University of California, San Diego, and an MBA from the MIT Sloan School of Management.

Montara has partnered with BioDuro, a trusted California-based CRDMO, to manufacture MT1110 drug substance for clinical development.

About Montara Therapeutics

Montara Therapeutics is a preclinical-stage biopharmaceutical company developing novel approaches to create safer and more efficacious treatments for neurological diseases. The company's proprietary BrainOnly™ platform enables brain-selective pharmacology by leveraging both existing and novel Brain-Targeting Chimeras (BrainTAC™) while restricting deleterious on-target/off-tissue peripheral activity. BrainOnly holds the potential to unlock numerous targets previously considered undruggable, greatly expanding the therapeutic options for patients in need of these therapies. Montara is supported by an outstanding group of investors, including founding investor SV Health Investors' Dementia Discovery Fund, Two Bear Capital, KdT Ventures, Dolby Family Ventures, and BEVC. For more information, visit montaratx.com.

About the TSC Alliance

The TSC Alliance is an internationally recognized nonprofit that improves quality of life for everyone affected by tuberous sclerosis complex by catalyzing new treatments, driving research toward a cure and expanding access to lifelong support. For more information, visit tscalliance.org.

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