



CuraSen Therapeutics Announces First Subject Treated with CuraAX (CST-3056) in a Phase 1 Clinical Trial

CuraAX Designed to Treat Neurogenic Orthostatic Hypotension (nOH) and Cognitive Impairment

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SAN CARLOS, Calif.--(BUSINESS WIRE)--CuraSen Therapeutics, Inc., a clinical-stage biopharmaceutical company developing oral, rapid onset, small molecule drugs to treat psychiatric and neurodegenerative diseases, announced today that it has treated its first subject with CuraAX, an alpha-1A adrenoceptor agonist, in a Phase 1 clinical trial. The company is developing CuraAX for patients with neurogenic orthostatic hypotension (nOH). Neurogenic orthostatic hypotension is a condition characterized by a significant, sudden drop in blood pressure upon standing, resulting in debilitating dizziness, fainting and cognitive impairment, due to inadequate blood flow to the brain. CuraAX is also expected to benefit cognition in patients with a range of neurologic conditions.

CuraAX, also known as CST-3056, is a proprietary, selective, CNS-penetrant alpha-1A adrenoceptor (α_{1A} -AR) agonist. The Phase 1 trial, whose objective is to assess the safety, tolerability and pharmacokinetics of CuraAX, will evaluate multiple dose levels of CuraAX in approximately 56 healthy volunteers, with an additional food effect cohort of six patients. The study will monitor a range of pharmacodynamic effects associated with α_{1A} -AR agonism to assess target engagement and potential therapeutic impact in nOH patients, as well as inform Phase 2 dose selection. Many patients with Parkinson's disease and related neurological disorders are affected by nOH.

"Current treatments for nOH are limited given their non-selectivity and/or indirect mode of action, leading to significant side effects; additionally, dosing regimens for standard of care products are demanding. CuraAX offers best-in-class potential that will provide stable and durable efficacy, improved safety and dosing convenience, with a differentiated cognitive benefit in these patients," said Kathleen Sereda Glaub, chief executive officer, CuraSen Therapeutics. "Additionally, nOH is an attractive fast-to-market opportunity addressing a significant orphan disease, particularly in nOH patients with Parkinson's disease, multiple system atrophy and pure autonomic failure."

CuraAX is being developed with funding from the Alzheimer's Drug Discovery Foundation (ADDF).

"Alzheimer's is a complex disease and as such, will need a complex solution that addresses the many underlying causes," said Howard Fillit, MD, co-founder and chief science officer at the ADDF. "CuraSen's alpha1a-adrenergic receptor agonist, CuraAX, represents a novel approach that addresses one of the earliest neuropathological symptoms of Alzheimer's disease, adrenergic decline due to locus coeruleus loss. The activation of adrenergic receptors on neurons and astrocytes, and pleiotropic effects has the potential to not only improve cognition, but to slow disease progression."

CuraSen is also developing CNS-selective beta2 adrenoceptor (β_2 -AR) agonist fixed-dose combinations with differentiated candidates, CuraCN (CST-103/CST-107) and CuraXN (CST-2032/CST-107). The company expects to advance CuraCN to a Phase 2b study later this year in major depressive disorder in older adults, many of whom also suffer from cognitive decline. CuraSen also is planning to evaluate these β_2 -AR agonists in other neurodegenerative diseases, including potentially Alzheimer's disease, progressive supranuclear palsy (PSP) and amyotrophic lateral sclerosis (ALS), to address cognitive impairment and other neurologic symptoms, as well as disease progression.

About CuraSen Therapeutics

CuraSen is focused on the development of new treatments for psychiatric and neurodegenerative diseases, including neurogenic orthostatic hypotension, major depressive disorder and neurodegenerative disease, including Alzheimer's disease, progressive supranuclear palsy (PSP) and amyotrophic lateral sclerosis (ALS). CuraSen's drugs are small molecule, oral tablets designed to directly activate certain receptor populations in the brain and periphery to compensate for decline of the adrenergic system driven by aging and disease. For more information, please visit www.curasen.com.

About The Alzheimer's Drug Discovery Foundation (ADDF)

Founded in 1998 by Leonard A. and Ronald S. Lauder, the Alzheimer's Drug Discovery Foundation is dedicated to rapidly accelerating the discovery of drugs to prevent, treat and cure Alzheimer's disease. The ADDF is the only public charity solely focused on funding the development of drugs for Alzheimer's, employing a venture philanthropy model to support research in academia and the biotech industry. The ADDF's leadership and contributions to the field have played a pivotal role in bringing the first Alzheimer's PET scan (Amyvid®) and blood test (PrecivityAD®) to market, as well as fueling the current robust and diverse drug pipeline. Through the generosity of its donors, the ADDF has awarded more than \$370 million to fund 765 Alzheimer's drug discovery and development programs, biomarker programs and clinical trials in 21 countries. To learn more, please visit: <https://www.alzdiscovery.org/>

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