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Phase 2a Clinical Data Show CuraSen Therapeutics' CuraAX (CST-3056) Met Primary Endpoint Demonstrating Statistically Significant Improvement in Standing Systolic Blood Pressure in Patients with Neurogenic Orthostatic Hypotension (nOH)

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Exploratory data presented at the 2026 37th International Symposium on the Autonomic Nervous System

CuraSen President and Chief Scientific Officer Anthony Ford, PhD, to deliver Burnstock Lecture

SAN DIEGO--(BUSINESS WIRE)--CuraSen Therapeutics, Inc., a biopharmaceutical company developing drug candidates for neurodegenerative diseases, today announced positive, exploratory Phase 2a data showing statistically significant, dose-dependent increases in standing systolic blood pressure with CuraAX (CST-3056) treatment in patients with symptomatic neurogenic orthostatic hypotension (nOH).

> *"In this Phase 2a proof-of-concept study, CuraAX maintained standing systolic blood pressure within a safe range — without an excessive increase in supine blood pressure. My patients felt better and were more mobile as a result."*
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Data are being presented today in a late-breaking oral presentation by Gabriel Vargas, MD, PhD, chief medical officer of CuraSen, at 11:00 am PT at the 37th International Symposium on the Autonomic Nervous System, held November 10-14 in San Diego. At the meeting, Anthony Ford, PhD, CuraSen's president and chief scientific officer, will also deliver the Plenary Burnstock Lecture on drug discoveries in purinergic and adrenergic signaling on November 13 at 9:30 am PT.

Neurogenic orthostatic hypotension is a serious, debilitating condition common in patients with Parkinson's disease (PD) and related neurodegenerative diseases (known as synucleinopathies). In these patients, the sympathetic nervous system fails to trigger the reflexive blood vessel constriction that normally maintains blood pressure. As a result, blood pressure suddenly drops upon standing or rising from a lying position, reducing blood flow to the brain. This often results in dizziness, lightheadedness, fainting and cognitive impairment, which can lead to dangerous falls, injuries and hospitalization.

CuraAX is an oral, selective, alpha-1A adrenoreceptor partial agonist designed to mitigate the significant drop in blood pressure upon standing or sitting up, while its partial agonism is intended to minimize the risk of blood pressure spikes when supine.

Study Design and Results

The Phase 2a study was a single-blind, five-day, inpatient, dose-escalation study that enrolled 12 patients with nOH due to Parkinson's disease, pure autonomic failure (PAF) or multiple system atrophy (MSA). The study objectives were to establish safety and tolerability, evaluate the hemodynamic effects of CuraAX during hourly 10-minute standing tests, as well as enable the selection of dose levels for the planned Phase 2b trial. Patients were treated with placebo, followed by single daily increasing doses of CuraAX. Additionally, patients completed daily orthostatic hypotension symptom assessments (OHSA). The study took place at multiple sites in the United States.

Key highlights:

- The primary endpoint of improvement in standing systolic blood pressure was met and was statistically significant for doses of 5, 10 and 20 mg:
    - On average, standing systolic blood pressure was maintained by increases of ~10-20 mmHg on active doses compared to placebo treatment

    - All patients responded with an improvement in standing systolic blood pressure, and those who were more hypotensive saw the greatest benefit of CuraAX treatment
    - Increases in supine systolic blood pressure changes were modest compared to those reported for midodrine, a standard-of-care treatment
- CuraAX demonstrated an acceptable safety and tolerability profile for the doses tested (5-40 mg) with adverse events that were mild or moderate and transient, including chills, tingling and goosebumps — known effects of α1A adrenergic agonism target engagement
- The dose range for the planned Ph2b study is confirmed as 5-20 mg
- Patients with greater pre-dose hypotension were able to stand longer in the 10-minute assessment periods on CuraAX

"Managing nOH is a constant balancing act: maintaining blood pressure enough to keep patients upright often drives it too high when they lie down," said Italo Biaggioni, MD, principal investigator, professor of medicine and pharmacology, and director of the Vanderbilt Autonomic Dysfunction Center. "In this Phase 2a proof-of-concept study, CuraAX maintained standing systolic blood pressure within a safe range — without an excessive increase in supine blood pressure. My patients felt better and were more mobile as a result. These results are consistent with CuraAX's selective and partial α1A adrenergic agonist mechanism, already revealing a differentiated treatment for the significant unmet need in nOH."

This clinical trial built upon previously reported Phase 1 results in 56 healthy volunteers. In that study, CuraAX was well tolerated up to the 90 mg maximum tolerated dose, demonstrated rapid and consistent absorption, and produced dose-dependent reductions in supine heart rate consistent with alpha-1A receptor engagement. IND-enabling and Phase 1 studies of CuraAX were supported by funding from the Alzheimer's Drug Discovery Foundation.

"These Phase 2a results with CuraAX, while exploratory, are an encouraging development for patients living with nOH and for CuraSen," said Kathleen Sereda Glaub, chief executive officer of CuraSen. "Unlike existing treatments limited by non-selective or indirectly acting mechanisms that impart variable exposure, significant safety concerns and demanding dosing regimens, CuraAX shows significant potential as a breakthrough nOH treatment with more stable and durable efficacy, reduced supine blood pressure elevation, improved convenience, and a potential pro-cognitive benefit via its CNS penetrance. We are excited to advance this best-in-class opportunity in a larger Phase 2 study."

About Neurogenic Orthostatic Hypotension, Pure Autonomic Failure and Multiple System Atrophy

Symptomatic neurogenic orthostatic hypotension is estimated to affect approximately 700,000 patients in the U.S. It commonly affects patients with Parkinson's disease and related synucleinopathies, including pure autonomic failure (PAF), a rare disorder of peripheral autonomic nerves, and multiple system atrophy (MSA), a progressive disease involving Parkinsonism, cerebellar ataxia and widespread autonomic failure. The fear of potential falls, for both patients and caregivers, often leads to greater inactivity, deconditioning and acceleration of disease progression. nOH is associated with higher morbidity and mortality in these populations, and represents a significant healthcare burden.

About CuraSen Therapeutics

CuraSen is focused on the development of new treatments for neurodegenerative diseases targeting mechanisms with broad applicability, including neurogenic orthostatic hypotension, Parkinson's and Alzheimer's diseases, and certain orphan indications such as amyotrophic lateral sclerosis (ALS). CuraSen's drugs are small molecules, given as 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 neurologic disease. For more information, please visit www.curasen.com.

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