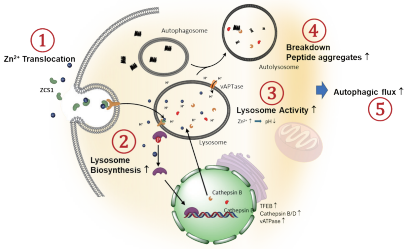
RS-2026-25502282

Nonclinical Study to Support IND Submission for ZC311, a Novel Lysosome-Activating Small Peptide Therapeutic Candidate for Amyotrophic Lateral Sclerosis (ALS)

Zincure Corp.

NEUROLOGY	Preclinical

Product Type	rProtein
Indication	Amyotrophic lateral sclerosis (ALS)
Target	Lysosome Activation
MoA(Mechanism of Action)	1. Migrate Zn^{2+} ions into lysosomes through endocytosis. 2. TFEB activation, increased expression of Cathepsin B/D and v-ATPase 3. Enhance Lysosomal Activity 4. Degradation of Toxic Protein Aggregates 5. Enhancement of Autophagic Flux 
Competitiveness	Zincure's drug candidate, ZCS1, demonstrates a novel mechanism of action, characterized by its delivery to lysosomes via endocytosis, where it facilitates lysosomal acidification and enhances protein degradation. This lysosomal activation enables ZCS1 to specifically target and degrade toxic protein aggregates implicated in neurodegenerative diseases. Notably, over 90% of ALS patients exhibit TDP-43 aggregates, and ZCS1 has been shown in cellular models to reduce their accumulation. ZCS1 is a modified short peptide with the capacity to cross the blood-brain barrier, exhibiting excellent metabolic stability, minimal CYP inhibition, and robust pharmacokinetic properties following both intravenous (IV) and subcutaneous (SC) administration. Additionally, ZCS1 has demonstrated an absence of adverse effects in both single-dose and 5-day repeated toxicity studies, as well as in Safety Panel 87 evaluations. In preclinical studies utilizing the SOD1-G93a mouse model, a representative model of ALS, ZCS1 extended survival by up to 3 weeks. Our program is strategically positioned at a critical inflection point, with **GLP non-clinical studies** in planning phase and **Chemistry, Manufacturing & Controls (CMC)** development actively underway.
Development Stage	Preclinical
Route of Administration	Subcutaneous

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