Spinogenix Granted FDA Orphan Drug Designation for SPG302 for the Treatment of Amyotrophic Lateral Sclerosis

SAN DIEGO, June 07, 2021 (GLOBE NEWSWIRE) -- Spinogenix, Inc. a pharmaceutical company focused on the development of novel synaptogenic small molecule therapies for central nervous system disorders and rare diseases, today announced it has been granted Orphan Drug Designation (ODD) for SPG302 in amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease) by the U.S. Food and Drug Administration (FDA). By obtaining orphan drug designation, SPG302 is now eligible for such benefits as exemption from FDA user fees and tax credits for clinical research.

In addition, Spinogenix reports the successful completion of pre-IND (Investigational New Drug) interaction with the FDA regarding the current development plan for SPG302. The FDA agreed to the overall development program including the first-in-human Phase 1/2 clinical study in ALS patients followed by a Phase 2/3 Pivotal trial based on safety/PK/biomarker data.

“Receiving orphan drug designation from the FDA for the treatment of ALS is an important milestone,” stated Stella Sarraf, Founding CEO at Spinogenix. “We are also pleased with the guidance from the FDA that now provides us with a clear clinical plan to rapidly advance our first-in-class drug to help ALS patients.”

SPG302 is an orally bioavailable, blood-brain barrier penetrating small molecule. Its mode of action regenerates lost synapses and has demonstrated improvements in cognitive and motor behaviors in multiple animal models of neurodegenerative disorders.

Dr. Merit Cudkowicz, Director of the Sean M. Healey and AMG Center for ALS at Mass General Hospital, commented, “We are thrilled that the FDA granted ODD to Spinogenix for their novel drug SPG302 and are excited to collaborate with them as they advance toward the clinic.”

About Spinogenix, Inc.:

Spinogenix was founded in 2016 with the mission to develop transformative therapeutics for diseases involving synaptic loss and dysfunction. Our drugs are designed to regenerate synapses, regardless of the underlying cause of synapse loss, and thereby reverse declines in cognitive and motor function to impact the disease and fundamentally change treatment paradigms. Synapse loss is associated with a variety of neurological and psychiatric diseases, such as ALS, Alzheimer’s disease, Parkinson’s disease, schizophrenia, and depression.

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