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Tranquis Therapeutics Announces Successful Completion of Phase 1 Clinical Trial of TQS-168

TQS-168 was well tolerated and demonstrated excellent pharmacokinetic properties

Tranquis plans to start a Phase 2 trial in ALS by the end of 2022

Tranquis Therapeutics, a clinical stage immuno-neurology company developing innovative medicines with the potential to revolutionize the management of neurodegenerative and aging-related diseases, today announced the completion of its Phase 1 clinical trial of TQS-168, a small molecule modulator of PGC-1a in development for the treatment of amyotrophic lateral sclerosis (ALS) and other neurodegenerative diseases.

Single and multiple doses of TQS-168 were well tolerated in 78 healthy volunteers, and no serious adverse events were reported. Adverse events were mild, transient, and did not lead to treatment discontinuation. TQS-168 also demonstrated excellent pharmacokinetic properties with adequate plasma exposures. Based on these results, Tranquis plans to initiate a Phase 2 clinical trial of TQS-168 in ALS by the end of the year.

"The data from our Phase 1 study of TQS-168 demonstrate that target plasma exposures can be achieved at dose levels that are well tolerated. The ability to reach human exposures that were associated with benefits in preclinical models of ALS bolsters our confidence in Tranquis' approach. We are developing an orally administered compound that targets PGC-1a in myeloid cells to treat neurodegenerative diseases in which dysfunctional myeloid cells play a key role in disease progression," said Jonas Hannestad, MD, PhD, Chief Medical Officer at Tranquis. "By the end of the year, we plan to advance TQS-168 into a Phase 2 study in people living with ALS, a devastating disease with high unmet need."

About TQS-168 And PGC-1a

TQS-168 is a PGC-1a-targeting small molecule in development for the treatment of ALS and other neurodegenerative diseases in which dysfunction of myeloid cells plays a critical role. PGC-1a is a transcriptional coactivator that regulates genes involved in cell energy metabolism, acting as a key regulator of mitochondrial biogenesis. When upregulated in dysfunctional myeloid cells, PGC-1a normalizes cell energy metabolism and immune function, giving it potential as a target in a variety of neurodegenerative diseases. TQS-168 showed survival and functional benefits in various animal models of neurodegenerative disease, including ALS and Parkinson's disease. TQS-168 also demonstrated compelling biomarker data, including increased PGC-1a gene expression, reduction of inflammatory monocytes and cytokines, and reduced levels of neurofilament light. *In vitro*, TQS-168 also shows specific immunomodulatory effects in myeloid cell lines and in white blood cells from people living with ALS.

Source: Tranquis.com