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Therapeutic potential of expanded SNK01 (activated autologous natural killer cells) post-stroke to reduce neuroinflammation, inflammation-mediated cell death, and damage

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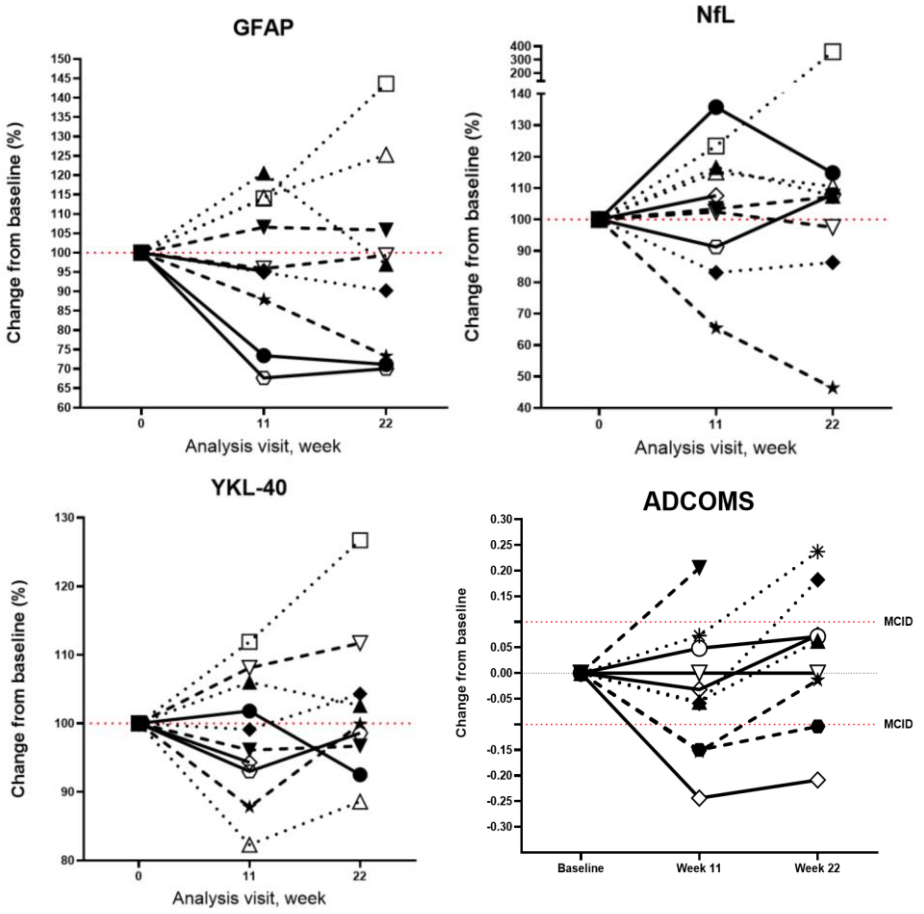
Background and Aims

Ischemic stroke triggers a neuroinflammatory cascade with increased autoreactive CD4+ and CD8+ T cells which cause secondary cell damage and further neurologic dysfunction. Glial fibrillary acidic protein (GFAP), a measure of astroglial activation after injury, Neurofilament Light (NfL) associated with axonal damage, and YKL-40 a novel inflammatory biomarker are all disproportionately elevated and prognostic in stroke patients. SNK01 is a novel non-genetically modified autologous natural killer cell therapy with increased cytotoxicity and activating receptor expression given via simple IV. SNK01 has been shown to cross the blood brain barrier to reduce neuroinflammation (remove autoreactive CD4+/CD8+ T cells) and decrease CSF levels of GFAP, Nf-L, and YKL-40 in patients with advanced neurodegenerative diseases.

Methods

In this proof-of-concept dose escalation pilot study, SNK01 was administered IV every three weeks to 13 patients with various neurodegenerative diseases (Alzheimer's, Parkinson's, and Post-Ischemic stroke). Primary endpoint was safety. Cognitive assessments and biomarkers were collected when possible.



Results

13 subjects were enrolled (6 males and 7 females). Two patients were treated on compassionate use.

Safety

No treatment related adverse events were observed.

Biomarkers

Despite suboptimal dosing for 2/3 of patients, a majority had reduction in neuroinflammation, with stable or improved CSF levels of GFAP, Nf-L, and YKL-40.

Clinical signs and symptoms

AD patients: 90% of patients had stable or improved cognitive function on ADCOMS.

Stroke patient (with right sided hemi-paralysis and aphasia): marked improvement in energy, mood, and verbal function.

Conclusions

SNK01 was safe and well tolerated.

SNK01 appears to cross the BBB to reduce neuroinflammation and will be studied further in the post-stroke setting.