Clinical Trial Approved for Ischemia-Tolerant Mesenchymal Stem Cells to Treat Alzheimer’s Disease

Stemedica Cell Technologies, Inc., received the U.S. Food and Drug Administration’s investigational new drug approval for a U.S.-based, Phase 2a clinical study using its allogeneic stem-cell therapy to treat patients with mild to moderate dementia due to Alzheimer’s disease.

Stemedica’s bone marrow-derived, allogeneic, ischemia-tolerant mesenchymal stem cells (itMSCs) are grown under hypoxic conditions that more closely resemble the environment in which they live in the body. Compared to other MSCs, itMSCs secrete higher levels of growth factors usually associated with angiogenesis and healing.

Promising results were achieved during a 3-year, intensive, pre-clinical research project. To evaluate the impact of an intravenous delivery of human MSCs on amyloid pathology, the well-established APPPS1 transgenic mouse model of Alzheimer’s disease was used. Intravenous delivery of itMSC safely reduced cerebral Abeta pathology in APPPS1 animals analyzed 1 week after the last injection. Old and young APPPS1 mice exhibited significantly decreased Abeta amyloidosis following itMSC treatments. Concomitantly, microglial activation was diminished in old and young itMSC-treated APPPS1 mice. No increase of vascular amyloid or manifestation of microhemorrhages was observed following the repeated intravenous itMSC delivery. Biodistribution analysis revealed that intravenously delivered itMSC migrate to the brain and could be detected with the highest value at 1 hour post-delivery, decreasing after 1 day and subsequently dropping below detection level at 1 week after the injection.


Entresto™ Approved to Reduce the Risk of Cardiovascular Death and Heart Failure

Novartis announced that the U.S. Food and Drug Administration (FDA) approved Entresto™ (sacubitril/valsartan) tablets, previously known as LCZ696, to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure and reduced ejection fraction. It is usually administered in conjunction with other heart failure therapies, in place of an angiotensin-converting-enzyme (ACE) inhibitor or other angiotensin receptor blocker.

The FDA’s decision is based on results from the 8,442-patient PARADIGM-HF study, the largest clinical trial ever conducted in heart failure. In the study, Entresto demonstrated clinically relevant and statistically significant superiority to ACE-inhibitor enalapril (Vasotec®), reducing the risk of cardiovascular death or heart failure hospitalization by 20% at a median follow up of 27 months. Entresto also improved overall survival by 16% versus enalapril, driven by the lower incidence of cardiovascular death.