UGA stroke treatment headed to clinical trial

First of its kind cell therapy targets brain inflammation caused by stroke

ATHENS, GA., USA, January 31, 2024 /EINPresswire.com/ -- A new therapeutic for stroke based on University of Georgia research will soon enter clinical trials.

The U.S. Food and Drug Administration cleared the new drug, known as AB126, to enter a Phase 1b/2a clinical trial, which is expected to begin in the first half of 2024 and will require significant funds to complete. This is the first stage of the trial and will test the safety and efficacy of the therapeutic in ischemic stroke patients.

Ischemic strokes are caused by clots that reduce or block blood flow to brain tissue, preventing the brain from getting adequate oxygen. These strokes are a leading cause of long-term disability and mortality worldwide.

Participants in the first phase of the trial will first undergo surgery to remove the clot that caused their stroke and then receive three infusions of the new treatment via IV. After the drug clears this phase, the goal is to use the new therapeutic as the primary treatment in those patients who can't access or don't qualify for other treatments.

"Our drug acts differently than current treatments in that it's not removing the clot; it's reducing the inflammation in the brain caused by the stroke," said Steven Stice, director of UGA's Regenerative Bioscience Center and co-founder of Aruna Bio, the company behind the new treatment.

Most stroke patients can't get clot-busting medication or surgery

About 800,000 Americans suffer a stroke each year, according to the Centers for Disease Control and Prevention. But only about 15% of those patients receive the gold standard of stroke care.

The only treatments currently available are a clot-busting medication that helps restore blood flow to the brain after a stroke or a minimally invasive surgery. But due to time constraints on the procedures and limited access to medical care, most stroke patients won't receive either.

When someone has a stroke, their brain cells start dying, explains Stice, who is also a professor in UGA's College of Agricultural and Environmental Sciences. As those cells die, they release damaging particles that cause extensive inflammation.

“What our product does is mop up those damaging particles,” Stice said. By doing that, the therapeutic also prevents other brain cells from dying due to inflammation.

While the brain can heal minor injuries on its own, the medication amps up the body’s ability to clean up the mess caused by the stroke by immediately reducing inflammation and ultimately replacing lost neurons as well.

New treatment is first neural stem cell therapy to target nervous system

The drug is the first of its kind to be used in the nervous system. Produced from neural stem cells, the therapeutic is incredibly small, which enables it to be given through a patient’s IV. The treatment then crosses from the blood into the brain, directly targeting those areas affected by the stroke.

Another key difference from other therapeutics on the market is the ability to give the drug to a patient multiple times. Typically, cell therapies can rile up the immune system, causing the body to attack itself.

But the new treatment doesn’t have that effect.

Being able to administer the treatment multiple times opens opportunities for long-term therapeutic uses—and not just in stroke treatment.

Stice and his colleagues are currently exploring the efficacy of the drug in treating amyotrophic lateral sclerosis, also known as ALS or Lou Gehrig’s disease. ALS is caused by aggressive inflammation in the nervous system, which causes progressive muscle weakness. There is no cure for the condition, and it’s almost always fatal.

Animal studies are promising in this application and suggest the drug is effective in reducing inflammation caused by the condition.

The researchers are also exploring the ability to administer the drug through a nasal spray, which would be a game changer for chronic inflammation-based diseases such as Alzheimer’s, Parkinson’s and traumatic brain injury.

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