# ALS Association Funds Study of Foralumab Nasal Spray

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Researchers at Brigham and Women's Hospital (BWH) have received a grant from the ALS Association to study foralumab nasal spray as a potential treatment for amyotrophic lateral sclerosis (ALS).

The Lawrence & Isabel Barnett Drug Development Program grant was awarded to the Ann Romney Center for Neurologic Diseases at BWH, Boston. This program funds preclinical research projects aimed at developing new ALS therapeutics or repurposing existing medications for ALS, particularly those with a high probability of reaching the clinic within three years.

At BWH, the funding will support studies in an animal model of ALS to determine if the anti-CD3 antibody foralumab can reduce the activation of microglia — the brain-resident immune cells that contribute to inflammation in ALS and other neurodegenerative diseases.

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“This prestigious research grant will be used to further study the role of intranasal anti-CD3 [antibody] in dampening the microglial activation which amplifies ALS disease progression,” Howard L. Weiner, MD, co-director of the Ann Romney Center and chairman of Tiziana Life Science’s scientific advisory board, said in a press release.

Weiner, who reformulated foralumab for nasal delivery, has been collaborating with Tiziana to develop the anti-CD3 intranasal antibody for a number of neurological diseases, including ALS, Alzheimer’s disease, and multiple sclerosis (MS).

“We have now seen the potential of intranasal foralumab to dampen microglial activation in three major neuroinflammatory-related diseases, which creates significant optionality for exploring its benefits in some of the most important and burdensome medical conditions of our time,” said Matthew W. Davis, MD, chief medical officer of Tiziana.

Foralumab is designed to reduce inflammation by targeting the CD3 protein on the surface of immune T-cells. In animal models, the medication suppressed activity of inflammatory T-cells and boosted the function of regulatory T-cells, which act to dampen the inflammatory activity of other immune cell types.

Excessive activation of microglia has been implicated in the abnormal immune responses that drive progression of several neurodegenerative diseases, including ALS, Alzheimer’s, and MS.

In MS, data from two patients with secondary progressive disease who received foralumab under an expanded patient access program showed reduced microglial activity after treatment, which was accompanied by multiple functional improvements.

Recently presented data from a mouse model of Alzheimer’s disease also indicated regulatory T-cells traveled into the brain after foralumab treatment, where they interacted with microglia. Genetic profiling of microglial cells showed an increase in the expression of genes associated with homeostatic processes, or processes involved in restoring normal function.

## Broader potential

“Intranasal foralumab has demonstrated potential across multiple central nervous system (CNS) indications,” said Gabriele Cerrone, executive chairman and interim CEO of Tiziana. CNS refers to the brain and spinal cord.

“We are encouraged by the preclinical research using an intranasal anti-CD3 [antibody] in the neuroinflammatory related diseases of ALS and Alzheimer’s, as well as the impressive clinical benefits we have already shown for foralumab in patients with multiple sclerosis,” Cerrone added. “While our initial focus is on our ongoing MS program which will continue to generate clinical read-outs, we are excited by foralumab’s potential to help highly debilitated ALS patients with limited therapeutic options and high unmet need.”