



Inflammasome Therapeutics' K8 Implant Cuts Lesion Growth by more than 50% in Geographic Atrophy after Three Months in Multi-Center Trial

Highlights

- Mean GA lesion area growth reduced by more than 50%
- No adverse safety signals
- Stabilization of visual acuity

Newton, MA (September 11, 2025) – Inflammasome Therapeutics (<https://www.inflam.com>), is a clinical-stage biotech company developing a new class of inflammasome inhibitors called Kamuvudines for ophthalmic and neurological conditions. Today, the company announced that the first of these drugs, K8, delivered via a sustained release intraocular implant for the treatment of Geographic Atrophy (GA), reduced GA lesion area growth by more than 50% following three months of treatment among an initial cohort of patients. This first human clinical trial for the drug is evaluating K8 in a multicenter 30-patient, six-month, safety and dose-escalation trial with three cohorts (NCT06164587). Patients with bilateral GA receive low, medium or high dose implants at baseline and three months in one eye, and untreated eyes serve as controls.

“Patients receiving the three-month, low dose, implant showed an average 53% reduction in lesion growth compared to untreated eyes at three months after a single injection,” said Paul Ashton, Ph.D., CEO and co-founder of Inflammasome Therapeutics. “The trial is relatively small (10 treated eyes in the first cohort) and was not designed to show statistical significance, so achieving such a large effect with a p value of 0.03 (mixed effect model) is extremely encouraging. Vision trends were also positive: eyes receiving the K8 implant had essentially stable vision,” he continued, noting that best corrected visual acuity increased an average of 1.4 ETDRS letters in K8-treated eyes, while untreated eyes continued to deteriorate, losing an average of 1.9 ETDRS letters.

“GA is a slowly progressive disease and over time we would expect vision in untreated eyes to continue to deteriorate,” Dr. Ashton said.

“We are also excited to announce that the mid-dose cohort has completed enrollment. That group will be followed by a high dose cohort, which is currently enrolling,” said Dr. Ashton.

“GA affects approximately one million people in the U.S. and more than eight million worldwide,” said Jayakrishna Ambati, M.D., co-founder of Inflammasome Therapeutics. He explained that in GA, multiple toxic substances trigger inflammasome activation that causes cells in the macula to slowly die (atrophy). Over time, the area of atrophy grows in size and can lead to vision loss. The two FDA-approved drugs for GA, SYFOVRE® and IZERVAY™, each targeting a different form of complement (one of the inflammatory factors), reduced lesion growth by approximately 20% with monthly intraocular injections, but unfortunately, did not reduce vision loss over 12 months in Phase III clinical trials. “We are encouraged by both the increased magnitude and duration of the effect seen so far with the K8 implant”, he continued.

“GA is a multifactorial disease in which many inflammatory toxic factors such as various forms of complement, amyloid beta, retrotransposons, oxidative stress are upregulated in the diseased eye, which causes upregulation of the inflammasome pathway and atrophy of cells in the macula. Over time, the area of atrophy grows and can lead to vision loss,” explained Dr. Ambati. “We believe the impressive result seen in this clinical trial and in numerous preclinical studies are due to the unique mechanism of K8, which inhibits activation of multiple inflammasomes and thereby blocks the effects of numerous inflammatory toxins, including complement.”

Inflammasome activation may be a key element in many neuroinflammatory and ocular diseases apart from GA, such as Alzheimer’s disease, ALS, Parkinson’s disease, multiple sclerosis and diabetic macular edema. K8 is a member of a new class of inflammasome-inhibiting drugs, called Kamuvudines, that were discovered by Dr. Ambati. They are derivatives of a class of anti-HIV drugs, NRTIs. NRTIs themselves have potential for repurposing as treatments for these diseases* but unfortunately have significant systemic toxicity that may hinder their use. Kamuvudines retain the anti-inflammasome activity of NRTIs but are designed to be safer. Pre-clinical work on Kamuvudines has been described in:

<https://www.science.org/doi/10.1126/science.1261754>

<https://www.science.org/doi/10.1126/sciadv.abj3658>

<https://www.nature.com/articles/s41392-021-00537-z>

Inflammasome Therapeutics (<https://www.inflam.com>) is a private, clinical-stage biotech company developing novel, first-in-class treatments for multiple ocular diseases, with additional potential as treatments in neurodegenerative conditions. The company has also initiated two additional Phase I/II trials with a second Kamuvudine, K9, which is orally

delivered. These trials are focused on Diabetic Macular Edema (NCT06781255) and Thyroid Eye Disease (NCT06467435).

*Recent news articles include:

<https://www.usnews.com/news/health-news/articles/2025-05-13/hiv-pills-might-prevent-alzheimers>

<https://www.yahoo.com/news/hiv-drugs-dramatically-lower-risk-051258290.html>

<https://www.nei.nih.gov/about/news-and-events/news/hiv-drug-can-improve-vision-patients-common-diabetes-complication>

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