Inflammasome Therapeutics Announces First Patient Dosed in Phase I Diabetic Macular Edema Study of the Dual Inflammasome Inhibitor K8

- *Phase 1 investigator-sponsored Clinical Trial: "Safety and Effect of Intravitreal Injection of a Derivative of Nucleoside Reverse Transcriptase Inhibitor in Subjects with Diabetic Macular Edema*
- *Study to assess safety and initial evidence of efficacy of the novel compound K8 in subjects with untreated DME*
- *First-in-class trial to treat DME with a dual inflammasome inhibitor that targets inflammasome activation in eye believed to be associated with DME*
- *Drug to be administered locally via a newly-designed sustained release implant system that enables continuous release of drug at pre-determined rates for a pre-determined period of time*
- *Marks first indication to enter clinical trials (a second clinical trial – in geographic atrophy – is about to recruit)*

Newton, MA (January 18, 2024) – Inflammasome Therapeutics (https://www.inflam.com), a clinical-stage, private company developing a new class of inflammasome inhibitor drugs, Kamuvudines, as therapies for prevalent, degenerative diseases, announced the first patient has been dosed in a Phase 1 study of one of the company's novel compounds in the treatment of diabetic macular edema (DME).

The 24-week study (ClinicalTrials.gov ID NCT05699759) is designed to assess safety and initial evidence of efficacy. This investigator-sponsored study, led by Dr. Michelle Abou-Jaoude of the University of Kentucky, is expected to be completed this year and will enroll five patients. Primary outcome measurements include:

- Mean change in central subfield thickness from baseline
- Mean change in BCVA (best-corrected visual acuity) as defined by the ETDRS scale
- Any adverse effects within the study period

"This marks the second clinical study for our Kamuvudines, and both are utilizing our newly designed sustained release implant system that will allow the drug to be released directly at the retina at a predetermined release rate. We initially are targeting a time period of three months," said Dr. Paul Ashton, CEO of Inflammasome Therapeutics. Late in 2023, the company announced it would be entering the clinic with a similar implant for treatment of Geographic Atrophy (GA), an advanced form of Dry Age-related Macular Degeneration.

In the United States, there are an estimated 750,000 individuals with DME. This number is expected to rise as the population ages, since diabetes (specifically Type 2) risk increases as one gets older. DME may occur in patients with either Type 1 or Type 2 diabetes. The market for DME drugs is a multi-billion dollar one, led by the anti-VEGF drugs that are injected frequently into the eye, as well as intravitreal implants, normally containing steroids. "Kamuvudines are unique in that they inhibit both NLRP3 and NLRC4, two inflammasomes thought to underlie the inflammatory processes responsible for disease progression in DME," said Dr. Ashton.

Dr. Ashton noted that his co-founder of Inflammasome Therapeutics, Dr. Jayakrishna Ambati, has spent more than a decade leading research into the activity of inflammasomes in triggering a variety of ophthalmic conditions as well as other neurodegenerative diseases such as amyotrophic lateral sclerosis (ALS, Lou Gehrig's disease), Parkinson's disease, and other degenerative conditions. By chemically altering the structure of the nucleoside reverse transcriptase inhibitors (NRTIs), Dr. Ambati and his team of scientists developed derivatives that form a new class of drugs in this category – with the same inflammasome-inhibiting action but none of the toxicity (as shown in numerous preclinical studies).

"In diabetic eye disease, metabolic stress (from diabetes) causes upregulation of various inflammasomes that then cause inflammation, which leads to retinal damage and swelling. Current therapies target the swelling but our drug is the first to target multiple inflammasomes," explained Dr Ambati.

Recent scientific research indicates that inflammasome activation may be the cause of neuroinflammatory diseases such as Alzheimer's disease, Parkinson's disease, ALS, and Multiple Sclerosis, among many others. These diseases continue to be challenging for the development of effective treatments. "Because of the abundant scientific evidence pointing to inflammasome activation as the cause of the processes that give rise to these diseases, we have been developing Kamuvudines that are specifically designed for these neurological diseases and can penetrate into the brain and CNS from a simple oral tablet," explained Dr. Ashton. "We look forward to entering the clinic with these for one or more of these indications this year."

Inflammasome Therapeutics (https://www.inflam.com) was founded by Jayakrishna Ambati, M.D. and Paul Ashton, Ph.D. to advance therapies for prevalent, degenerative diseases and to advance novel delivery technologies for sustained release of therapeutic agents and compounds. The company combines scientific excellence with proven development expertise and works to create breakthrough products via a mixture of licensing agreements and internal development. Inflammasome Therapeutics has identified and licensed a series of molecules – Kamuvudines – that successfully inhibit inflammasome activation in cell cultures and animal models and is advancing its drugs into the clinic for treatment of eye diseases and neurodegenerative conditions such as Alzheimer's disease, ALS and MS.

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