



InflammX Therapeutics Submits IND Amendment to enable Clinical Studies with orally dosed Xiflam™, its NLRP3 Inflammasome-targeting Program in Retinal and Kidney Disease.

- Submission of the IND Amendment enables the commencement of a Diabetic Macular Edema (DME)/Diabetic Nephropathy (DN) Phase 2b clinical trial to be undertaken by the DRCR Retina Network, which is supported by the National Eye Institute.
- Two additional Phase 2b ophthalmic clinical trials will be conducted by InflammX, designed for treatment of the intermediate stage of “dry” Aged-Related Macular Degeneration (iAMD) and the Geographic Atrophy (GA) form of “dry” AMD. These are planned to commence by year end 2022.
- InflammX is set to become the most clinically advanced company targeting clinical autoinflammation secondary to dysregulation of the inflammasome.

Tampa, FL, September 29, 2022 - InflammX Therapeutics, Inc. (InflammX), a privately held biopharmaceutical company, today announced the submission of an Investigational New Drug (IND) Amendment to U.S. Food and Drug Administration (FDA), to enable the commencement of clinical trials with Xiflam™, an orally administered NLRP3 inflammasome inhibitor with broad application that is formulated as a tablet. InflammX will initially focus on the ophthalmic indications of Diabetic Macular Edema (DME), the intermediate stage of Aged-Related Macular Degeneration (iAMD) and the Geographic Atrophy (GA) form of AMD.

The DRCR Retina Network clinical study in DME will be undertaken at clinical sites in the U.S. Since patients in the trial will be orally dosed, the therapeutic effect of Xiflam on biomarkers of active kidney disease, will be measured as an integral component of the study.

“InflammX technology, developed at the University of Auckland, New Zealand, is designed to treat conditions in which the assembly and subsequent recycling of the inflammasome pathway of inflammation results in autoinflammatory disease,” said Dr Brian Levy, Chief Executive Officer of InflammX. “We are excited to be evaluating a novel mechanism of action with an orally-administered therapeutic to treat patients with retinal diseases, which are leading causes of vision loss. And since our drug is orally dosed, a major advantage for patients is that both eyes will be treated concomitantly without the need for injections. We are also excited to be undertaking trials targeting a major source of autoinflammation, making InflammX the most clinically advanced company to treat diseases related to the dysregulated inflammasome.”

Dr. Philip J Rosenfeld, Professor of Ophthalmology at the Bascom Palmer Eye Institute and a Board Member of InflammX commented that “Xiflam™’s unique mechanism of action and its ability to cross the blood-brain and blood-retinal barriers provide a novel therapeutic approach for treating retinal diseases with an orally administered tablet capable of treating both eyes simultaneously. This disruptive technology can provide a much needed clinical alternative for treating the millions of patients with diabetic retinopathy and age-related macular degeneration.”



David S. Boyer, MD, renowned ophthalmologist with Retina-Vitreous Associates Medical Group and a Board Member of InflammX noted “the InflammX approach of targeting the inflammasome in ophthalmology is unique and has substantial support in the scientific community. I am personally very excited to be involved in targeting the ocular inflammation in DME and GA. I believe that Xiflam™ will be a game-changing therapy.”

About InflammX

InflammX is a privately held biopharmaceutical company that is targeting the NLRP3 inflammasome pathway of inflammation. InflammX has identified the key disease-related upstream trigger for inflammasome activation, and our therapeutics target this trigger. Its lead product, Xiflam™, will enter Phase 2B clinical trials in fourth-quarter 2022. InflammX has a follow on pre-clinical peptide program that also targets the dysregulated NLRP3 inflammasome which will be developed following additional funding being raised.

About the NLRP3 Inflammasome

The inflammasome is a multiprotein complex that forms inside cells. It is essential for function of the innate immune system, the body's first response to any insult such as pathogenic organisms, foreign substances, or sterile stressors. Although only discovered in 2002, the inflammasome has been identified as a common pathway of autoinflammation in multiple major disease conditions.

The inflammasome has two triggering signals, a priming signal (the initial insult) and an activation signal that enables its assembly. Activation and assembly of inflammasome complexes result in the release and recycling of multiple pro-inflammatory cytokines.

If not terminated, this dynamic perpetuated recycling of the immune response contributes to long lasting autoinflammation in several disease states.

About Xiflam

Xiflam is an orally available small molecule that blocks the activation signaling to break the persistent recycling of the inflammasome that is a hallmark of those diseases.

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