

Kiora Announces Publication of Phase 1 Study Demonstrating Safety, Tolerability and Anti-Inflammatory Activity of KIO-101 in the Treatment of Inflammation of the Eye

Encinitas, California-(March 8, 2024) - Kiora Pharmaceuticals, Inc. (NASDAQ: KPRX), (“Kiora” or the “Company”) announced the publication of results from a Phase 1 double-masked study of KIO-101, a potent, non-steroidal anti-inflammatory agent. KIO-101 contains the same active molecule as KIO-104, which belongs to a family of potent anti-inflammatory agents. The study showed that a 12-day treatment of KIO-101 topically at multiple doses was well tolerated in healthy volunteers and patients with inflammation of the eye. There was a significant decrease in conjunctival hyperemia in the treatment group compared to the placebo group. Conjunctival hyperemia, a sign of ocular inflammation, is due to a variety of non-infectious and infectious causes. The paper was published in the journal, *Pharmaceutics* (2024, 16(3), 367 | <https://doi.org/10.3390/pharmaceutics16030367>)

Kiora’s KIO-100 family of compounds contain the same proprietary active molecule but are uniquely formulated for a specific condition and region of the eye being targeted. KIO-101 is the designation for topical delivery and KIO-104 is the designation for intravitreal injection (directly into the eye). Kiora’s active molecule belongs to a class of drugs known as DHODH inhibitors, including teriflunomide, an FDA-approved drug that has been prescribed to hundreds of thousands of patients with multiple sclerosis. DHODH inhibitors are believed to reduce the production of T-cells, a type of immune cell that, in certain conditions like autoimmune disease, can cause damaging inflammation. Delivering KIO-101 or KIO-104 locally in the eye aims to reduce T-cell-related inflammation without the associated potential side effects of systemic anti-inflammatory drugs.

“These results support the therapeutic potential of our molecule to address inflammation in the eye,” explained Eric Daniels, MD, Chief Development Officer, Kiora. “A Phase 2 trial of KIO-104 is expected to start later this year to treat posterior non-infectious uveitis, a rare inflammatory condition of the retina. Because uveitis can lead to vision loss, there’s an important need for new treatment options beyond chronic steroid injections or systemic autoimmune disease drugs currently being used today. Beyond uveitis, we see an opportunity to target additional retinal inflammatory diseases that could similarly benefit from a non-steroidal therapeutic option.”

The published study involved a double-masked, placebo-controlled, randomized, parallel-group design that consisted of two parts. In Part I, 24 healthy volunteers received single or multiple administrations of KIO-101 eye drops in ascending doses (0.05%, 0.15% or 0.30%). Part II involved 21 patients with conjunctival hyperemia who received either 0.15% KIO-101 eye drops or vehicle (2:1) twice daily for 12 consecutive days. The findings include the following:

- KIO-101 eye drops were well tolerated in all subjects.
- There were no serious adverse events. All adverse events were transient and considered mild to moderate.
- In the highest dose cohort (0.30%), epistaxis occurred in two subjects after multiple instillations.
- In Part II, after 12 days of treatment with 0.15% KIO-101, conjunctival hyperemia decreased by 1.1 ± 0.27 points in the KIO-101 treated group versus 0.6 ± 0.79 points in the placebo group ($p = 0.0385$).
- From baseline to day 12, the Ocular Surface Disease Index Questionnaire (OSDI) score decreased by 20.3 points in the treatment group, while in the placebo group decreased by 14.0 points ($p=ns$).

Kiora is planning a Phase 2 clinical trial of KIO-104 to be administered by intravitreal injection directly into the retina for the treatment of posterior non-infectious uveitis. The Company previously reported positive results from a Phase 1 study of KIO-104 for treatment of posterior non-infectious uveitis. Posterior non-infectious uveitis is a rare autoimmune disease characterized by inflammation of the retina, choroid, vitreous, or optic nerve, and can result in severe vision loss. It can result from many underlying causes, which may include the ocular manifestation of certain autoimmune diseases.

About Kiora Pharmaceuticals

Kiora Pharmaceuticals is a clinical-stage biotechnology company developing and commercializing products for the treatment of orphan retinal diseases. KIO-301 is being developed for the treatment of retinitis pigmentosa, choroideremia, and Stargardt disease. It is a molecular photoswitch that has the potential to restore vision in patients with inherited and/or age-related retinal degeneration. KIO-104 is being developed for the treatment of posterior non-infectious uveitis. It is a next-generation, non-steroidal, immuno-modulatory, and small-molecule inhibitor of dihydroorotate dehydrogenase.

In addition to news releases and SEC filings, we expect to post information on our website, www.kiorapharma.com, and social media accounts that could be relevant to investors. We encourage investors to follow us on Twitter and LinkedIn as well as to visit our website and/or subscribe to email alerts.

Forward-Looking Statements

Some of the statements in this press release are “forward-looking” and are made pursuant to the safe harbor provision of the Private Securities Litigation Reform Act of 1995. These “forward-looking” statements include statements relating to, among other things, the potential of the KIO-100 family to address inflammation in the eye, the expected timing of a Phase 2 trial of KIO-104, and the development and commercialization efforts and other regulatory or marketing approval efforts pertaining to Kiora’s development-stage products,

including KIO-104, as well as the success thereof, where such approvals or success may not be obtained or achieved on a timely basis or at all. These statements involve risks and uncertainties that may cause results to differ materially from the statements set forth in this press release, including, among other things, the ability to conduct clinical trials on a timely basis, the ability to obtain any required regulatory approvals, whether future trials will yield similar results for participants, market and other conditions, and certain risk factors described under the heading “Risk Factors” contained in Kiora’s Annual Report on Form 10-K filed with the SEC on March 23, 2023, or described in Kiora’s other public filings. Kiora’s results may also be affected by factors of which Kiora is not currently aware. The forward-looking statements in this press release speak only as of the date of this press release. Kiora expressly disclaims any obligation or undertaking to release publicly any updates or revisions to such statements to reflect any change in its expectations with regard thereto or any changes in the events, conditions, or circumstances on which any such statement is based, except as required by law.

Contact Information:

Investors@kiorapharma.com



To view the source version of this press release, please visit <https://www.newsfilecorp.com/release/200945>