

Kiora Receives Approval to Initiate KLARITY, a Phase 2 Clinical Trial of KIO-104 for the Treatment of Retinal Macular Edema

Encinitas, California–(February 11, 2025) – Kiora Pharmaceuticals, Inc. (NASDAQ: KPRX) (“Kiora” or the “Company”) today announced it received regulatory approval to initiate KLARITY, a Phase 2 clinical trial to investigate KIO-104 in patients with retinal macular edema, a condition where build-up of fluid behind part of the retina can be associated with adverse vision changes. KIO-104 is a potent, locally delivered small molecule being developed as an alternative to steroids or systemic anti-inflammatory drugs, both of which have known shortcomings.

KLARITY is a multi-center, open label study in up to 28 patients. The primary objective is to evaluate safety and tolerability of repeated doses of KIO-104 administered by standard intravitreal injection. Secondary endpoints will evaluate the magnitude of macula edema reduction, improvement in visual acuity and the systemic pharmacokinetic profile of KIO-104. The study will enroll patients with macular edema secondary to one of the following diseases: diabetic retinopathy, non-infectious uveitis, retinal vein occlusion, or post pseudophakic cataract surgery. The study will be performed in two parts as follows:

- Part A (Dose Optimization) will assess the safety and efficacy of three injections administered once every two weeks in 8 subjects. Cohort 1 will receive 3.5 µg doses of KIO-104 while Cohort 2 will receive 10 µg doses of KIO-104.
- Part B (Cohort Expansion) will investigate different dosing regimens (2-week versus 4-week intervals) in the remaining subjects at a dose selected from Part A.

“Our aim is to further demonstrate the therapeutic potential of KIO-104. The need for a local, steroid-sparing approach to treating conditions associated with retinal inflammation, including macular edema, remains at the forefront of clinical retinal research. We believe KIO-104 can fulfill that role and provide meaningful benefit to patients suffering from reduced vision due to macular edema,” said Eric J. Daniels, MD, MBA, Chief Development Officer at Kiora. “Our drug is differentiated by its ease of delivery and the clinically validated immunomodulatory pathway upon which it acts. The class of compounds, DHODH inhibitors, are disease modifying, clinically effective and commercially successful as systemic treatments for multiple sclerosis and rheumatoid arthritis. We are now looking to expand the potential of this therapeutic class for use in inflammatory conditions of the eye.”

KIO-104 works by suppressing T cell numbers and function in the eye responsible for driving inflammation. Specifically, KIO-104 inhibits the mitochondrial enzyme, DHODH, which plays a crucial role in the synthesis of key building blocks of DNA and RNA. Through this nucleotide starvation, T cell replication is significantly impaired. In addition, these building blocks serve as key co-factors required for multiple T cell functions, including producing pro-inflammatory

cytokines.

About Kiora Pharmaceuticals

Kiora Pharmaceuticals is a clinical-stage biotechnology company developing advanced therapies for retinal disease. We target critical pathways underlying retinal diseases using innovative small molecules to slow, stop, or restore vision loss. 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 retinal inflammation. It is a next-generation, non-steroidal, immuno-modulatory, and small-molecule inhibitor of dihydroorotate dehydrogenase (DHODH).

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 X 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, Kiora’s ability to execute on development and commercialization efforts and other regulatory or marketing approval efforts pertaining to Kiora’s development-stage products, including KIO-104 and KIO-301, as well as the success thereof, with such approvals or success may not be obtained or achieved on a timely basis or at all, the sufficiency of existing cash on hand to fund operations for specific periods, the projected cash runway, the ability to timely complete planned initiatives for 2024, including phase 2 clinical development of KIO-301 and KIO-104, the potential for KIO-301 to be the first treatment options for patients with inherited degenerative diseases like RP, Kiora’s plans to further fund development of KIO-104, the potential for KIO-104 to reduce inflammation, the timing of topline results from clinical trials of KIO-104, the potential for KIO-104 to apply to other retinal inflammatory diseases, the anticipated readout dates for Kiora’s clinical trials and their likelihood of success, and expected trends for research and development and general and administrative spending in 2024. These statements involve risks and uncertainties that may cause results to differ materially from the statements set forth in this press release the ability to conduct clinical trials on a timely basis, 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 25, 2024 or described in Kiora’s other public filings including on Form 10-Q filed with the SEC on November 8, 2024. 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.

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