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Kiora Pharmaceuticals Receives Investigational New Drug Application Approval to Expand Phase 1b Study of KIO-301 in Inherited Retinal Diseases; To Enroll Patients with Choroideremia and Additional Patients with Late-Stage Retinitis Pigmentosa

Encinitas, California--(Newsfile Corp. - October 3, 2023) -[Kiora Pharmaceuticals](#) (NASDAQ: KPRX) has received Investigational New Drug Application approval in Australia to enroll up to six additional patients in the ABACUS study of [KIO-301](#). ABACUS was initially designed to evaluate patients with Retinitis Pigmentosa (RP). Based on encouraging findings previously shared, Kiora sought this approval to evaluate additional patients with late-stage RP as well as those with late-stage Choroideremia (CHM), a rare form of hereditary retinal degeneration. Plans remain for Kiora to report topline results on the first six RP patients in the ABACUS study on November 4th at the [American Academy of Ophthalmology retina subspecialty day](#).

Kiora previously reported preliminary data in late-stage RP patients finding KIO-301 safe and tolerable with promising signs of efficacy. KIO-301 is a small molecule photoswitch, a first-in-class therapeutic with the potential to restore vision across several inherited retinal diseases (IRDs), regardless of underlying gene mutations.

"Data collected from additional patients will provide further insight to guide continued stages of clinical development," explained Eric Daniels, M.D., Chief Development Officer at Kiora. "We are now in a position to expand this 'gene mutation-agnostic approach' to generate further proof-of-concept in patients with late-stage CHM. The common denominator in both RP and CHM is rod and cone degeneration, and that is precisely why KIO-301 has a good opportunity to make an impact."

[Choroideremia](#) is a rare X-linked, recessive, inherited retinal disorder affecting approximately 1 in 50,000 individuals. It is caused by a loss-of-function mutation in the CHM gene. Initial symptoms include loss of night vision and often leads to severe vision impairment and blindness. Kiora is working with the Choroideremia Research Foundation (CRF), the world's largest not-for-profit organization dedicated finding a cure for CHM, to assist in a deeper understanding of the disease as well as access to CRFs patient database and thought leaders to assist in trial enrollment and future study designs.

"Adding CHM into ABACUS is consistent with our sharpened focus in addressing orphan retinal diseases," added Dr. Daniels. "Running programs in multiple IRDs will allow for operational efficiencies while developing therapeutics for a major unmet need, like CHM. Our work with CRF brings the top thought leaders in the space and access to patient databases to ensure we are giving the best chance of success to the development of KIO-301 in CHM."

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, and Kiora also plans to develop KIO-301 for Choroideremia and Stargardt's Disease. It is a molecular photoswitch that has the potential to restore vision in patients with inherited and/or age-related retinal degeneration. Kiora plans to develop KIO-104 for the treatment of posterior non-infectious uveitis. It is a next-generation, non-steroidal, immuno-modulatory and small molecule inhibitor of Dihydroorotate Dehydrogenase (DHODH) with what Kiora believes is best-in-class picomolar potency and a validated immune modulating mechanism (blocks T cell proliferation and proinflammatory cytokine release).

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 development and commercialization efforts and other regulatory or marketing approval efforts pertaining to Kiora's development-stage products, including KIO-301 and KIO-104, as well as the success thereof, with such approvals or success may not be obtained or achieved on a timely basis or at all, and Kiora's ability to reach a quorum at the adjourned Special Meeting. 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, 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.

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