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Kiora Pharmaceuticals Granted Orphan Drug Designation for KIO-301, an Investigational Drug for the Treatment of Retinitis Pigmentosa (RP)

Salt Lake City, Utah--(Newsfile Corp. - March 18, 2022) - Kiora Pharmaceuticals, Inc. (NASDAQ: KPRX), ("Kiora" or the "Company") has received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for its investigational treatment of Retinitis Pigmentosa, KIO-301. Retinitis Pigmentosa is a rare, inherited genetic eye disease that can lead to severe loss of vision due to degeneration of rods and cones. Kiora expects to initiate clinical trials of KIO-301 in Q3 2022. Orphan drug designation provides for facilitated development discussions with the FDA, tax credits for qualified clinical trials, a waiver on the user fee for marketing application (PDUFA fee) and extended market exclusivity of up to seven years as a way to encourage companies to develop treatments for rare conditions.

"This designation reflects the need for new treatment options for the estimated 80,000 patients living with Retinitis Pigmentosa in the U.S. alone," said Brian M. Strem, Ph.D, President and CEO of Kiora. "While RP can be caused by a variety of gene mutations, our small molecule KIO-301 has the potential to be used as a standalone therapy regardless of the underlying mutation(s) or in combination with next-generation gene-specific therapies. We plan to begin a Phase 1b clinical trial in Australia later this year before initiating larger studies in the U.S. and worldwide."

KIO-301 (benzyl ethyl aminoazobenzene quaternary ammonium) is a visible light-sensitive small molecule that acts as a reversible 'photoswitch', specifically designed to restore the eyes' ability to perceive and interpret light in visually impaired patients. KIO-301 selectively enters specific retinal ganglion cells (those downstream of degenerated rods and cones) and converts them into light sensing cells, capable of signaling the brain as to the presence or absence of light.

Retinitis pigmentosa is a rare inherited disease that typically presents with loss of low light vision, followed by reduced visual field (loss of peripheral vision) and eventually loss of central vision. The condition affects approximately one out of every 3,000 to 5,000 people and is caused by more than 50 distinct genetic subtypes from more than 150 gene mutations.

About Kiora

Kiora is a clinical-stage biotechnology company developing and commercializing products for treating ophthalmic diseases. KIO-301 is a molecular photoswitch that has the potential to restore light perception in patients with inherited and/or age-related retinal degeneration.

KIO-101 is a next-generation, non-steroidal, immuno-modulatory and small molecule inhibitor of Dihydroorotate Dehydrogenase ("DHODH") with best-in-class picomolar potency and a validated immune modulating mechanism (blocks T cell proliferation and proinflammatory cytokine release) designed to overcome the off-target side effects and safety issues associated with other DHODH inhibitors. In addition, Kiora is developing KIO-201, a modified form of the natural polymer hyaluronic acid, designed to accelerate corneal wound healing. For more information, please visit www.kiorapharma.com.

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 products, including KIO-101, KIO-201 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. 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, 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, 2021 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.

Investor Contact
Francina Agosti, Ph.D.
(617) 546-0742
fagosti@reportablenews.com

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