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Kiora Pharmaceuticals Receives European Orphan Medicinal Product Designation for KIO-301 for the Treatment of Inherited Retinal Dystrophies

Encinitas, California--(Newsfile Corp. - July 30, 2024) - Kiora Pharmaceuticals (NASDAQ: KPRX) ("Kiora" or the "Company") today announced it has received Orphan Medicinal Product Designation from the European Medicines Agency (EMA) for the treatment of a group of inherited retinal diseases (IRDs) that include retinitis pigmentosa (RP), choroideremia and more. The broad designation covers KIO-301, a small molecule photoswitch, for the treatment of non-syndromic rod-dominant retinal dystrophies. This classification of dystrophies, in simplified terms, refers to rare diseases from underlying genetic mutations resulting in predominantly and primarily the degeneration of rod photoreceptors, the cells responsible almost entirely for night vision as well as peripheral and non-color vision. In RP, which today has no approved therapeutics, rods degenerate first followed by degeneration of cone photoreceptors, the cells responsible for color and central vision. This degenerative process causes partial or severe loss of vision and may result in complete blindness. There are approximately 92 million rods in the human eye compared to approximately 6 million cones.

"This designation provides Kiora and our development and commercialization partner, Théa Open Innovation, with at least ten years of market exclusivity, exclusive of patent protection, in Europe. This is in addition to other regulatory and market access benefits," said Eric Daniels, M.D., Chief Development Officer of Kiora Pharmaceuticals. "With Orphan Drug Designation already granted in the U.S., KIO-301 is well positioned for expediated regulatory guidance, review, and market exclusivity in two major marketplaces. We are finalizing the design and planning to initiate the Phase 2 trial of KIO-301 (ABACUS-2) later this year."

In addition to market exclusivity, additional benefits of Orphan Medicinal Product Designation includes:

- A centralized process for EU market approval;
- Reduced or waived fees for regulatory activities; and
- EMA scientific advice and protocol assistance to optimize trial design.

The European Union provides Orphan Medicinal Product Designation to incentivize drug developers to bring products for rare diseases to market that may otherwise not be developed. The designation is granted after a critical review and only if a drug candidate meets specific criteria, which incudes but is not limited to the following:

- The investigational therapy is medically plausible and intended to treat a serious or life-threatening disease; and

- The condition affects no more than 5 in 10,000 people in the EU.

Kiora's upcoming ABACUS-2 trial of KIO-301 for vision restoration in individuals with RP, will be a multi-center, double-masked, randomized, controlled, multiple-dose study. KIO-301 is a small molecule photoswitch designed to selectively confer light-sensing capabilities to retinal ganglion cells following the degeneration of photoreceptors in inherited retinal diseases like retinitis pigmentosa. This represents a novel, gene-mutation agnostic, non-cell or gene therapy approach to addressing vision loss in IRDs.

In January 2024, Kiora, along with Théa Open Innovation (TOI), a sister company of the global ophthalmic specialty company Laboratoires Théa (Théa), agreed to an exclusive worldwide co-development and commercialization agreement, excluding Asia, for KIO-301 in the treatment of retinal 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, 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, and Kiora's plans to further fund development of KIO-104. 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 satisfy the closing conditions related to the offering, 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 May 10, 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.

Contacts:
Investors
investors@kiorapharma.com

Media
kiora@crowepr.com

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