

## **Kiora Pharmaceuticals Provides 3rd Quarter 2022 Business and Financial Update; Dosing of KIO-301 in Phase 1 Trial for Retinitis Pigmentosa to Begin Before Year's End**

Salt Lake City, Utah–(November 9, 2022) – Kiora Pharmaceuticals, Inc. (NASDAQ: KPRX), (“Kiora” or the “Company”) today is providing a business update and reporting financial results for the three and nine months ended September 30, 2022.

### ***Management Discussion:***

“We’re advancing a diverse development pipeline of three differentiated assets across rare and narrowly-defined patient populations requiring new treatment options for ophthalmic disease,” said Brian M. Strem, Ph.D., President and Chief Executive Officer of Kiora.

“Following our recent capital raise, we are prioritizing our resources on developing KIO-301 as the first treatment that could potentially restore vision in patients with Retinitis Pigmentosa (RP). This strategy we believe provides the most cost-effective and time-efficient path to a substantive clinical milestone in an indication for which there are no approved drugs as well as a tremendous patient need. Our development team, led by Eric Daniels, M.D., has undertaken a significant effort to lay the foundation for the ABACUS clinical study, which has been approved to initiate enrollment and will imminently begin dosing the first of the planned six RP patients. Dr. Daniels and his team have dedicated their efforts to ensuring state-of-the-art testing and evaluation tools and protocols are in place to ensure we optimize the findings to inform the next stages of development.

“KIO-301 is a versatile compound with applications beyond a standalone treatment for RP. As a small molecule photoswitch, it has the potential to be used in combination with gene therapies currently in development to repair specific mutations associated with RP. In addition, it has the potential to address other inherited forms of blindness as well as age-related retinal degenerative diseases.

“Our development activities for KIO-201 are similarly focused on a rare ophthalmic indication, Persistent Corneal Epithelial Defects (PCED). This ocular surface condition is characterized by non-healing eye surface wounds. A small proof-of-concept study is currently underway to help inform our next steps. As a potential orphan indication, it offers us the pathway to cost-effectively bring a product to market with extended exclusivity.

“Our third product, KIO-101, addresses a non-orphan ophthalmic patient population, a subset of autoimmune patients whose disease manifests on the ocular surface, initially focusing on patients with Rheumatoid Arthritis (RA). This ocular presentation of autoimmune disease is found in approximately 500,000 people in the U.S. and is one of the most common extra-articular complaints among RA patients. Results from two previous ocular inflammation

studies have been reported this year demonstrating clinical proof-of-concept of our DHODH-inhibitor as a safe and effective non-steroidal ocular immune modulator. Our strategy is to commit resources immediately towards designing and securing approvals to initiate a Phase 2 clinical trial in Q4 2022 and begin enrollment of patients in 2023.”

### ***Upcoming milestones:***

Key upcoming milestones Kiora expects to achieve include the following:

- Complete enrollment in the ABACUS study, a first-in-human six-patient Phase 1 trial evaluating KIO-301 as a potential treatment for retinitis pigmentosa.
- Report initial results from patients in Cohort 1 of ABACUS.
- Complete enrollment in our Phase 2 study of KIO-201 in patients with Persistent Corneal Epithelial Defects.
- Receive orphan drug designation for KIO-201 in PCED, which would provide extended market exclusivity for up to seven years in the U.S. in this indication.
- Initiate a Phase 2 trial for KIO-101 for the ocular presentation of Rheumatoid Arthritis.

### ***Milestones Year-to-Date:***

Notable milestones that Kiora has achieved year-to-date include:

- Approval to initiate the ABACUS study, a first-in-human clinical trial for KIO-301, which is intended to restore lost vision in patients with Retinitis Pigmentosa.
- Receipt of orphan drug designation for KIO-301 by the US FDA in March 2022, providing extended market exclusivity for up to seven years in the U.S.
- Initiation of enrollment in a Phase 2 study of KIO-201 in patients with Persistent Corneal Epithelial Defects.
- Receipt of a U.S. patent covering hydrogel-based sustained release platforms, inclusive of KIO-201, to enable controlled release of antibiotics to treat ocular diseases.
- Published results from a Phase 1 trial of KIO-100 in uveitis, an ophthalmic inflammatory disease, providing clinical proof-of-concept of Kiora’s DHODH-inhibitor.
- The presentation of full results from the KIO-101 Phase 1b clinical trial, which support the planned Phase 2 clinical trial for the treatment of the ocular presentation of Rheumatoid Arthritis.
- Appointed Melissa Tosca as the Executive Vice President of Finance to oversee finance, SEC reporting and accounting functions.

### **Financial Results**

Research and development expenses were \$1.3 million and \$2.6 million for three and nine months ended September 30, 2022, respectively, compared to \$1.6 million and \$4.3 million for the three and nine months ended September 30, 2021, respectively. The year over year

decrease was primarily due to the Company's ability to claim an Australian research and development tax credit in 2022, partially offset by increased activities related to the commencement of patient dosing in the ABACUS study. Similarly, a sequential decrease in the third quarter of 2022 was due primarily to the Company's ability to claim an Australian research and development tax credit, partially offset by increased trial activities related to KIO-301.

General and administrative expenses were \$2.0 million and \$5.5 million for the three and nine months ended September 30, 2022, respectively, compared to \$1.3 million and \$3.9 million for the three and nine months ended September 30, 2021, respectively. This increase was primarily due to an increase in audit and consulting fees, travel and other office and corporate expenses offset by a decrease in personnel-related expenses.

Net loss was \$5.1 million and \$11.1 million for the three and nine months ended September 30, 2022 compared to \$3.0 million and \$7.6 million for the three and nine months ended September 30, 2021, respectively. In the third quarter of 2022, there was a non-cash expense of \$1.4 million due to a change in fair value of the Warrant liability. Net cash used in operating activities for the first 9 months of 2022 was \$8.3 million.

Cash and cash equivalents were \$4.8 million as of September 30, 2022 with an additional \$1.6 million in tax receivables related to Austrian and Australian research and development tax credit incentive programs. Subsequent to the end of the quarter, Kiora has received approximately \$0.5 million in cash from warrant exercises.

## **About Kiora Pharmaceuticals**

Kiora Pharmaceuticals is a clinical-stage biotechnology company developing and commercializing products for the treatment of ophthalmic diseases. KIO-301 is being developed for the treatment of retinitis pigmentosa. It is a molecular photoswitch that has the potential to restore vision in patients with inherited and/or age-related retinal degeneration. KIO-101 is being developed for the treatment of the Ocular Presentation of Rheumatoid Arthritis ("OPRA"). 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) designed to overcome the off-target side effects and safety issues associated with commercially available DHODH inhibitors. In addition, Kiora is developing KIO-201, a chemically cross-linked form of the natural polymer hyaluronic acid, designed to accelerate corneal wound healing.

In addition to news releases and SEC filings, we expect to post information on our website, [www.kiorapharma.com](http://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 anticipated use of the net proceeds of the offering, the development and commercialization efforts and other regulatory or marketing approval efforts pertaining to Kiora’s development-stage 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, the potential ability of KIO-301 to restore vision in patients with RP, the expecting timing of the ABACUS study, the potential of KIO-301 to be used in combination with gene therapies and to address other inherited forms of blindness and retinal degenerative diseases, the potential of KIO-201 to receive an orphan indication, and Kiora’s ability to achieve the specific milestones described herein. 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, market and other conditions and certain risk factors described under the heading “Risk Factors” contained in Kiora’s Amendment No. 1 to Annual Report on Form 10-K/A filed with the SEC on July 7, 2022 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



To view the source version of this press release, please visit

<https://www.newsfilecorp.com/release/143583>