



## **Kairos Pharma Enters Agreement with PreCheck Health Services to Develop Biomarkers to Identify Patients Responsive to ENV105 to Target Cancer Drug Resistance in Prostate and Lung Cancer Patients**

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LOS ANGELES, Sept. 24, 2024 (GLOBE NEWSWIRE) -- Kairos Pharma Ltd. (NYSE American: KAPA), a clinical-stage biopharmaceutical company, announces a groundbreaking collaboration with PreCheck Health Services Inc., a CLIA-certified and CAP-accredited clinical laboratory specializing in genetic sequencing. The partnership focuses on the development of companion biomarkers for Kairos Pharma's cancer therapy, ENV105, which targets prostate and lung cancers. This strategic agreement aims to advance the precision of patient screening and therapy monitoring for Kairos Pharma's Phase 1 and Phase 2 clinical trials, with the aim of advancing cancer treatment by identifying patients who will benefit most from ENV105.

Kairos Pharma and PreCheck Health Services will utilize advanced molecular diagnostics to corroborate and further develop biomarkers previously identified in a Phase 2 clinical trial. These biomarkers are designed to predict patient responses to ENV105 prior to treatment, offering a more personalized approach to cancer care. Under the agreement, PreCheck will analyze biopsy tissues and circulating tumor cells from patients enrolled in Kairos Pharma's ongoing clinical trials, including a Phase 2 randomized, multi-institutional trial in prostate cancer and a Phase 1 trial in lung cancer. The goal is to confirm the predictive capabilities of these biomarkers and to discover new biomarkers that can identify suitable candidates for the novel therapy.

The collaboration will rely on PreCheck's proprietary SolidTumorCheck+ platform, which allows for gene expression profiling of tumor biopsies. This technology will be employed to examine samples from patients with both lung and prostate cancer. Furthermore, the analysis of circulating tumor cells aims to offer non-invasive insights, potentially leading to the development of liquid biopsy tests for future patient screening and therapy monitoring.

### **Clinical Trials at the Forefront of Oncology Research**

The biomarkers will be tested in two key clinical trials:

- **NCT05401110:** A Phase 1 trial targeting patients with EGFR-driven lung cancer who have developed resistance to osimertinib. Pre-treatment biopsies will undergo somatic gene expression profiling using the SolidTumorCheck+ platform to identify biomarkers that can predict a favorable response to ENV105.
- **NCT05534646:** A phase 2 trial for patients with castrate-resistant prostate cancer (CRPC) who have shown resistance to multiple androgen receptor signaling inhibitors. Here, the focus will be on the somatic profiling of circulating tumor cells and tumor biopsies to confirm previously identified biomarkers and identify any new ones tied to ENV105's efficacy.

Both trials aim to integrate cutting-edge biomarker analysis into treatment plans, ensuring that patients most likely to benefit from ENV105 are accurately identified.

### **Development of Companion Diagnostics**

A companion diagnostic is an FDA-approved test which can identify patients that are most likely to benefit from a therapeutic product. One of the key outcomes of this partnership is the creation of a companion diagnostic for ENV105. PreCheck will develop a three-gene PCR analysis or other genetic tools to predict patient response to the therapy. This diagnostic will seek FDA approval as a critical tool for the identification of suitable patients with prostate or lung cancer, guiding inclusion for treatment in Phase 3 clinical trials.

Dr. Neil Bhowmick, Kairos Pharma's Chief Scientific Officer, expressed optimism about the collaboration, stating, "Leveraging PreCheck's vast experience in genetic testing provides a considerable advance in the development of our therapies. The integration of their expertise will significantly enhance our ability to identify patients who will benefit from ENV105 and guide the development of non-invasive liquid biopsy tests."

### **A Step Forward in Cancer Treatment**

The development of these companion biomarkers is poised to transform how cancer patients, particularly those with resistant forms of prostate and lung cancer, are treated. The integration of biomarkers and liquid biopsy technologies will allow for more precise targeting of therapies, reducing the likelihood of ineffective treatments and increasing the probability of positive outcomes.

Dr. John Yu, Kairos Pharma's CEO, commented, "This collaboration is an exciting step forward for Kairos Pharma. By working with PreCheck Health Services, we are advancing our mission to provide personalized cancer treatment solutions. The biomarkers we develop will enable us to tailor therapies to individual patients, improving their chances of a successful response to ENV105."

### **About Kairos Pharma Ltd.**

Based in Los Angeles, California, Kairos Pharma Ltd. (NYSE American: KAPA) is at the forefront of oncology therapeutics, utilizing structural biology

to overcome drug resistance and immune suppression in cancer. With a diverse pipeline of investigational therapies, the company is committed to reversing the harmful effects of cancer on the body's immune system and improving patient outcomes through innovative treatment options. For more information, visit [kairospharma.com](http://kairospharma.com).

#### **About PreCheck Health Services Inc.**

PreCheck Health Services Inc. is a CLIA-certified and CAP-accredited clinical laboratory known for its expertise in genetic sequencing. PreCheck provides advanced diagnostic services to support precision medicine, particularly in the field of oncology. To learn more about their offerings, visit [precheckhealth.com](http://precheckhealth.com).

This strategic agreement marks a significant step in the development of personalized cancer therapies, offering hope to patients with prostate and lung cancer who have few remaining treatment options. Through the power of biomarkers and genetic analysis, Kairos Pharma and PreCheck Health Services are working together to shape the future of oncology treatment, with ENV105 leading the way.

#### **CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS**

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. You can identify forward-looking statements as those that are not historical in nature, particularly those that use terminology such as "may," "should," "expects," "anticipates," "contemplates," "estimates," "believes," "plans," "projected," "predicts," "potential" or "hopes" or the negative of these or similar terms. The reader is cautioned not to rely on these forward-looking statements. If underlying assumptions prove inaccurate, or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Kairos Pharma. We base these forward-looking statements on our expectations and projections about future events, which we derive from the information currently available to us. Such forward-looking statements relate to future events or our future performance. In evaluating these forward-looking statements, you should consider various factors, including: our expectations regarding the success and/or completion of our Phase 1 and Phase 2 clinical trials; our success in completing newly initiated clinical trials, commence new trials, and obtain regulatory approval following the conclusion of such trials; challenges and uncertainties inherent in product research and development; and the uncertainty regarding future commercial success. These and other factors may cause our actual results to differ materially from any forward-looking statement. Forward-looking statements are only predictions. The forward-looking statements discussed in this press release and other statements made from time to time by us or our representatives, may not occur, and actual events and results may differ materially and are subject to risks, uncertainties and assumptions about us, including those described in Kairos Pharma's prospectus filed with the SEC. We are not obligated to publicly update or revise any forward-looking statement, and Kairos Pharma is not required to update any forward-looking statement as a result of new information or future events or developments, except as required by U.S. federal securities laws.

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