



# Kairos Pharma Announces Positive Safety Results from Phase 2 Trial of ENV-105 in Advanced Prostate Cancer

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LOS ANGELES--(BUSINESS WIRE)-- Kairos Pharma, Ltd. (NYSE American:KAPA), a clinical-stage biopharmaceutical company focused on innovative cancer therapeutics, today announces positive safety results from its ongoing Phase 2 clinical trial of ENV-105 (carotuximab) in patients with metastatic castration-resistant prostate cancer (mCRPC). The interim safety analysis of the trial demonstrated that ENV-105, a first-in-class CD105 antagonist, was well tolerated when combined with standard of care hormone therapy, apalutamide, from the first ten enrolled patients. Thus far, there have been no dose-limiting toxicities or unexpected adverse events reported to date. In addition, the treatment-related side effects were manageable with standard supportive care. Notably, no Grade 3 or 4 toxicities were observed.

"The favorable safety profile observed in this Phase 2 study is encouraging, as it validates our belief in ENV-105's clinical potential and supports continued development in a patient population with limited effective treatment options," said John Yu, MD, Kairos Pharma CEO.

With one million men in the U.S. being diagnosed with prostate cancer annually, and millions more worldwide, the development of resistance to current hormone therapies is a growing unmet need with an increasingly aging population. Castration-resistant prostate cancer refers to tumors that grow despite receiving hormone blocking agents. Treatment options remain limited after hormone therapies fail. Kairos Pharma seeks to provide a safe and effective alternative for these patients with ENV-105.

The randomized Phase 2 trial aims to enroll 100 patients in total, and is presently accruing patients at Cedars-Sinai Medical Center, City of Hope, and Huntsman Cancer Center. The study is designed to evaluate the safety, tolerability, and early signs of efficacy of ENV-105, a CD105 antagonist, in men whose disease has progressed following standard hormone-based therapies. Interim efficacy data from the trial are expected to be reported in September 2025.

Kairos Pharma plans to engage with regulatory agencies to discuss the design of a potential pivotal Phase 3 study,

based on emerging data.

For more information about the study, visit <https://clinicaltrials.gov/search?cond=Prostate%20Cancer&intr=Carotuximab>.

Kairos Pharma is a biopharmaceutical company advancing a pipeline of targeted therapies for cancer patients with high unmet medical needs. Our mission is to bring safe, effective, and science-driven solutions that improve the efficacy of existing standard of care to the most challenging forms of cancer.

## 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 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 Annual Report on Form 10-K and our other filings made 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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