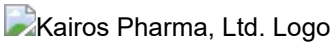

Kairos Pharma Presents on Phase 2 Trial of ENV-105 in Advanced Prostate Cancer at European Society Medical Oncologists (ESMO) Meeting

2025-10-20

Interim efficacy analysis highlights potential value of combination therapy of ENV-105 and apalutamide following positive safety data

LOS ANGELES--(BUSINESS WIRE)-- Kairos Pharma, Ltd. (NYSE American: KAPA), a clinical-stage biopharmaceutical company focused on innovative cancer therapeutics, today presents on the positive interim efficacy data from its ongoing Phase 2 clinical trial of ENV-105 (carotuximab) in patients with metastatic castration-resistant prostate cancer (mCRPC) at the annual European Society Medical Oncologists meeting in Berlin, Germany.

An interim efficacy analysis from the ongoing trial with ENV-105, a first-in-class CD105 antagonist, is being tested for safety and early efficacy in men with metastatic prostate cancer resistant to standard hormone therapy. Despite progression on prior hormonal therapies, the trial showed clinical benefit when combining ENV-105 with hormone therapy, apalutamide, in 86% of treated patients. All responders remained progression-free for at least four months and half remained progression-free beyond one year. Notably, seven of nine evaluable patients experienced a reduction in PSA levels from baseline.

“The positive safety profile and initial clinical benefit we’ve seen through our extensive interim analysis validates the comprehensive mechanism of action studies that preceded this clinical study, demonstrating how ENV-105 restores a patient’s ability to respond to hormone therapy,” said Dr. Neil Bhowmick, CSO of Kairos Pharma.

Edwin Posadas, Director of the Experimental Therapeutics Program and the Medical Director of the Center for Uro-Oncology Research Excellence at the Cedars-Sinai Cancer Institute, leads the randomized Phase 2 trial that is currently accruing up to 100 patients at Cedars-Sinai Medical Center, City of Hope Cancer Center, and the Huntsman Cancer Institute. The 13.7 median PFS (progression free survival) achieved by imaging with the ENV-105 and apalutamide combination reported would suggest an improvement over current alternatives of chemotherapy and radioligand therapy, in terms of disease control as well as tolerability. Kairos Pharma seeks to provide a safe and effective therapy with ENV-105 for the over 3 million men with hormone-resistant prostate cancer worldwide.

About Kairos Pharma, Ltd.

Based in Los Angeles, California, Kairos Pharma Ltd. (NYSE American: KAPA) aims to work at the forefront of oncology therapeutics, utilizing structural biology to overcome drug resistance and immune suppression in cancer. Our lead candidate, ENV105, is an antibody that targets CD105 – a protein identified as a key driver of resistance to various cancer treatments. Elevation of CD105 in response to standard therapy results in resistance and disease relapse. ENV105 aims to reverse drug resistance by targeting CD105 and restore the effectiveness of standard therapies across multiple cancer types. Currently, ENV105 is in a Phase 2 clinical trial for castrate-resistant prostate cancer and a Phase 1 trial for lung cancer aimed at addressing significant unmet medical needs. For more information, visit kairospharma.com.

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 trial; 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, as amended, and our other filings made with the Securities and Exchange Commission. 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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