



Kairos Pharma Ltd. Announces Completed Enrollment of the Safety Arm of Its Phase 2 Clinical Trial of ENV105 in Metastatic, Castration-Resistant Prostate Cancer

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Company expects safety data readout in 2025 as Randomized Arm continues enrollment at key medical centers

LOS ANGELES--(BUSINESS WIRE)-- Kairos Pharma, Ltd. (NYSE American: KAPA), a clinical-stage biopharmaceutical company (the "Company"), announces the completion of the safety lead-in of its Phase 2 clinical trial of ENV105 for the treatment of metastatic, castration-resistant prostate cancer. The trial, titled, "Phase II study of Apalutamide with Carotuximab (ENV105) in Metastatic, Castration Resistant Prostate Cancer," began with the safety lead-in, which combined apalutamide, a standard of care for prostate cancer, with the Company's compound ENV105.

The second part of the study, which randomizes patients to receive either apalutamide alone or in combination with ENV105 is ongoing. The Company expects to announce the safety and efficacy data readout from the safety arm of the trial beginning in the first half of 2025.

"This is an important milestone in this trial as it helps to establish the safety and preliminary efficacy of the combination therapy with ENV105, which is essential in order to proceed with the randomized portion of the trial. We are very pleased with the rate of our progress thus far and are grateful to our participating centers for their continued dedication to the trial," said John Yu, M.D., Kairos CEO.

The Company is also validating biomarkers throughout the study to best identify those patients believed to have the most benefit for the combination therapy. In the meantime, the Company continues to enroll patients for the randomization arm of the study at key cancer centers in Los Angeles and Salt Lake City. The trial is supported by Kairos Pharma Ltd. and a grant from the National Cancer Institute (NCI).

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 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 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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