Kairos Pharma Announces Strategic Collaboration with Bayer to Enhance XOFIGO Activity in Metastatic Prostate Cancer

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Combination Targets a $570M–$1.3B Addressable Global Market; ENV-105 Phase 2 Data Show 86% Clinical Benefit Rate in Resistant mCRPC

LOS ANGELES--(BUSINESS WIRE)-- Kairos Pharma, Ltd. (NYSE American: KAPA), a clinical-stage biopharmaceutical company focused on overcoming cancer drug resistance, today announced a strategic collaboration with Bayer to evaluate Kairos Pharma's lead antibody ENV-105 (carotuximab), a first-in-class CD105/BMP signaling inhibitor, in combination with Bayer's XOFIGO (radium-223 dichloride) in metastatic castration-resistant prostate cancer (mCRPC) involving bone.

Kairos Pharma's current programs with ENV-105 include a Phase 1 trial in EGFR-driven non-small cell lung cancer and a Phase 2 trial for castrate resistant prostate cancer. Last year, Kairos announced positive interim efficacy data from the Phase 2 trial showcasing median progression-free survival was more than 13 months, a significant improvement from standard of care. These data were presented at the 2025 ESMO Congress in Berlin. XOFIGO is the first and only FDA-approved alpha-emitting radiopharmaceutical for mCRPC with symptomatic bone metastases and is currently advancing through additional combination studies, including the Phase III PEACE-3 trial, which demonstrated a 24% reduction in mortality risk when combined with enzalutamide (HR 0.76; p=0.009).

"Drug resistance remains one of the greatest challenges in advanced prostate cancer, and XOFIGO, like many standard-of-care therapies, can lose efficacy over time," said John Yu, M.D., Kairos Pharma Chief Executive Officer. "ENV-105 has already demonstrated the ability to re-sensitize tumors to existing treatments with a strong safety profile, and this collaboration with Bayer represents a major milestone in our mission to deliver more durable and more effective treatment regimens for patients with metastatic prostate cancer."

Previous published work has demonstrated the efficacy of ENV-105 in radiation sensitization in prostate cancer preclinical models. CD105 is upregulated in response to standard androgen receptor inhibition and in responses to ionizing radiation, driving pro-survival BMP-SMAD signaling pathways underlying therapy resistance. Targeting

CD105 with ENV-105 re-sensitizes resistant tumors and may extend the duration and depth of response to XOFIGO's targeted alpha therapy.

Neil Bhowmick, Ph.D., Chief Scientific Officer and Principal Investigator stated, "CD105's role as a central resistance mechanism validated now across multiple drug classes makes this collaboration scientifically compelling and clinically timely, given XOFIGO's recent Phase III momentum."

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. Kairos Pharma's lead candidate, ENV-105, is an antibody that targets CD105—a protein identified as a key driver of resistance and disease relapse in response to standard therapy. ENV-105 aims to reverse drug resistance by targeting CD105 and restore the effectiveness of standard therapies across multiple cancer types. 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.

investors@kairospharma.com

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