



Kairos Pharma Provides Shareholder Update

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Company makes important progress in 2025 and looks ahead into 2026

LOS ANGELES--(BUSINESS WIRE)-- [Kairos Pharma Ltd.](#) (NYSE American: KAPA), a clinical-stage biopharmaceutical company focused on innovative cancer therapeutics, provides an overview of key 2025 milestones and outlook into 2026 in a Letter to Shareholders from CEO John Yu, M.D. presented below.

To our valued Kairos Pharma Shareholders,

This year, Kairos has been focused on executing its Phase 2 randomized clinical trial of ENV105 in combination with apalutamide in patients with advanced metastatic prostate cancer. The study is designed to evaluate the safety, tolerability, and early signs of efficacy of ENV105, a CD105 antagonist, in men whose disease has progressed following standard hormone-based therapies.

To date, we have [announced positive interim safety and efficacy results](#), as well as conducted an informative online KOL event that featured experts both within and external from our clinical program. Despite progression on prior hormonal therapies, the trial showed clinical benefit when combining ENV105 with apalutamide in 86% of treated patients to date. 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 13.7 median PFS (progression free survival) achieved by imaging with the ENV105 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. 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 4 or 5 toxicities were observed.

Our Chief Scientific Officer Neil Bhowmick [presented these findings](#) at the European Society Medical Oncologists (ESMO) Meeting last month, showcasing that our lead candidate may significantly lengthen the effectiveness of standard of care in these indications. We continue to recruit patients to the study with up to 100 patients expected to be enrolled across our esteemed centers, Cedars-Sinai Medical Center, City of Hope Cancer Center, and the Huntsman Cancer Institute.

Other highlights from this year include:

- [Presentation of new Phase 1 data on ENV-105 combination therapy in non-small cell lung cancer at the World Lung Cancer Conference](#)
- [Presentation of new data on small molecule G1TR ligand agonist KROS-101 as a promising cancer immunotherapy at the American Society of Clinical Oncology \(ASCO\) 2025 Annual Meeting](#)
- [Receipt of a Department of Defense grant to support the study of lead candidate ENV105 to prevent drug resistance in lung cancer](#)
- [Publishing of a peer-reviewed publication in Drug Resistance Updates highlighting the critical role of CD105 \(endoglin\) in mediating resistance to osimertinib, a frontline treatment for EGFR-mutant non-small cell lung cancer](#)
- [Presentation of preclinical data on investigational compounds KROS101 and KROS401 further supporting both compounds' potential as therapeutics for melanoma and glioblastoma during the American Association for Cancer Research Immuno-Oncology \(AACR IO\) meeting](#)
- [Receipt of Department of Defense funding for research of ENV205, a groundbreaking new drug to treat chemotherapy drug resistance and cachexia](#)

As Kairos continues to showcase the potential of our candidates, we anticipate the following key milestones for 2026, including:

- Continuing to execute the second phase of our randomized clinical trial of ENV105 in prostate cancer, with enrollment expected to be completed by the end of the year
- Continue to conduct our Phase 1 clinical trial of ENV105 in non-small cell lung cancer, announcing key progress updates as available
- Announce peer-reviewed publication of the interim safety and efficacy data from the Phase 2 ENV105 trial in a high impact journal
- Announcement of key partnerships within the cancer drug development and delivery space
- Pursuit of further advancement of investigational and preclinical candidates like ENV205, KROS101, and KROS401, among others
- Presenting key data on our ongoing programs at national scientific meetings

In parallel, Kairos Pharma continues to focus on getting our compelling story to investors and stakeholders in the biopharma space by presenting at forums such as the D. Boral Inauguration Investor Conference, the Maxim Fireside Chat, and the HC Wainwright 27th Global Investment Conference. We have participated in the European BIO, BIO, and China BIO with productive partnering discussions.

In the meantime, we continue to feel confident in the paradigm-shifting potential of our therapeutics, which are based on the breakthrough science developed by our officers. We believe these therapeutics will show the potential to make a lasting impact by stopping the relentless spread of human neoplastic disorders.

We continue to be grateful to our partners and our shareholders. We look forward to expanding upon our science, while providing value to our shareholders both in the near- and long-term. We look forward to continuing to provide you with updates on our progress and development as we move forward.

Sincerely,

John Yu, M.D.

CEO

Kairos Pharma

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. 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.

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 Annual Report on Form 10-K and 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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