Kairos Pharma Announces Positive Interim Efficacy Analysis of Phase 2 Trial of ENV105 in Advanced Prostate Cancer with Median Progression Free Survival of Over One Year

2025-09-18

Interim efficacy analysis highlights potential value of combination therapy of apalutamide and ENV105 following positive safety data

Company to host virtual KOL discussion today to provide additional perspective on data and the Company's lead program

LOS ANGELES--(BUSINESS WIRE)-- Kairos Pharma, Ltd. (NYSE American: KAPA), a clinical-stage biopharmaceutical company focused on innovative cancer therapeutics, today announces positive efficacy data from its ongoing Phase 2 clinical trial of ENV105 (carotuximab) in patients with metastatic castration-resistant prostate cancer (mCRPC). Kairos Pharma is hosting a virtual KOL (key opinion leader) event to provide perspectives on this data at 5 p.m. ET / 2 p.m. PT today. Interested participants can sign-up to receive the webcast link here.

All patients enrolled in the trial had already failed at least one other hormone therapy modality. This predetermined interim analysis covers the same 10 patients from the safety-arm of the trial, with all patients having failed at least one androgen receptor inhibitor hormone therapy prior to acceptance. Two of the ten patients withdrew from the trial for unrelated events. Of the eight remaining patients, the median progression-free survival was more than 13 months, with five of the eight patients continuing treatment without progression. Seven of nine patients demonstrated a decrease of their prostate-specific antigen (or PSA) from baseline.

The interim efficacy analysis of the trial demonstrated that ENV105, a first-in-class CD105 antagonist, in combination with standard of care hormone therapy apalutamide demonstrated a progression-free survival (PFS) of 13 months. Notably, the trial is powered to show a 45% improvement in the PFS. This translates to an increase in PFS from 3.7 to 6.7 months. This mark was far exceeded by the ENV105/ Apalutamide combination. The four-month timeframe is significant as 2nd or 3rd line standard of care hormone therapy has a 3.7-month median efficacy, as reported by the CARD trial (New Eng J. Med [2019] 381:2506). The same study also showed the use of chemotherapy

(cabazitaxel) provided eight months' PFS, by imaging, accompanied with greater toxicity.

"Our therapeutics, targeting cancer resistance, continue to showcase the potential to revolutionize the way we treat cancer patients," said Dr. John Yu, CEO of Kairos Pharma. "While this is only interim data, we are excited to bring together the principal investigators and other industry experts for an important event this afternoon to lay out the primary benefits of our compound, and demonstrate the clinical need filled by ENV105."

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 ENV105, a CD105 antagonist, in men whose disease has progressed following standard hormone-based therapies.

The interim safety analysis of the same trial, announced in July of this year, demonstrated that ENV105 was well tolerated when combined with standard of care hormone therapy, apalutamide, from the first 10 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 Grade 4 toxicities were observed.

Kairos Pharma will host a premier KOL event later today at 5 p.m. ET / 2 p.m. PT to discuss diverse perspectives on the interim efficacy results. Speakers at the KOL event include Dr. Neil Bhowmick, President and Chief Scientific Officer at Kairos Pharma; Dr. Umang Swami, Associate Professor in the Division of Oncology, Department of Internal Medicine at the Huntsman Cancer Institute; Dr. Richard Lee, Clinical Co-Director, The Claire and John Bertucci Center for Genitourinary Cancers at Massachusetts General Hospital, Harvard Medical School; and Dr. 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.

With one million men in the US diagnosed with prostate cancer each year, and millions more worldwide, the development of resistance to current hormone therapies has created 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 ENV105.

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.

CORE IR
investors@kairospharma.com
https://investors.kairospharma.com/overview/default.aspx

Source: Kairos Pharma, Ltd