First Take

Kairos Pharma, Ltd. (KAPA)

July 15, 2025

Price: $0.69; Market Cap (M): $12; *7/14/2025 Close*

Rating: Buy; Price Target: $12.00

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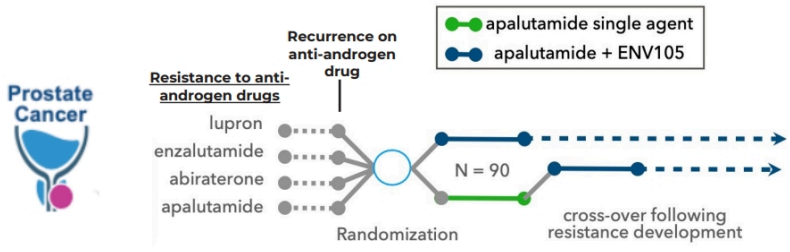
ENV-105 Advances in mCRPC Phase 2 Study With Positive Safety Update; Interim Efficacy Data Expected 3Q25

Positive safety update from Phase 2 study of ENV-105 in mCRPC; efficacy update next in 3Q25. This morning, Kairos announced a positive interim safety update from the ongoing randomized Phase 2 study of its lead asset, ENV-105(a first-in-class anti-CD105 antibody), in patients with metastatic castration resistant prostate cancer (mCRPC). Specifically, ENV-105 was well tolerated when combined with SoC hormone therapy, apalutamide (Erleada) (JNJ; not rated), from the first ten enrolled patients, the pre-specified number required for a safety readout. To date, there have been no dose-limiting toxicities (DLTs) or unexpected adverse events (AEs) reported. In addition, the treatment-related side effects were manageable with standard supportive care. Notably, no Grade 3 or 4 toxicities were observed. We remind investors, the Phase 2 study is currently enrolling patients at Cedar-Sinai Medical Center, City of Hope Cancer Center, and Hunstman Cancer Institute. The study is designed to evaluate the safety, tolerability, and early signs of efficacy of ENV-105 in men whose disease has progressed following apalutamide treatment. The study is targeting enrollment of 100 patients in total, to be randomized and given apalutamide as single agent or in combination with ENV-105 for 2 months (the single agent arm can crossover following resistance development). The primary endpoint of the study is progression free survival (PFS), and the secondary endpoint is companion biomarker confirmation. Per management, the benchmark for response is if PFS in the combination arm can go beyond 4 months (as 2L or 3L mCRPC typically become resistant ~2months) in 50% of patients. At 4 months, it is expected that patients on apalutamide would demonstrate tumor progression. Interim efficacy data from the trial are expected to be reported in 3Q25. Following this forthcoming data update, the company intends to meet with regulatory agencies to discuss a path forward to pivotal studies, including a potential Phase 3 study design. Today's safety update continues to bolster our confidence in the program and supports the continued advancement of ENV-105 in this patient population with a high unmet need.

ENV-105 in mCRPC: Randomized Phase 2 Study Design



Source: Company materials

DoD funds support advancement of ENV-105 in EGFR-driven NSCLC. Recently, Kairos announced that its academic partner, Cedars-SInai Medical Center, has received a U.S Department of Defense (DoD) grant to support the advancement of its lead asset, ENV-105 for the treatment of EGFR-driven NSCLC. Specifically, the company has secured $876,000 of non-dilutive financing from the DoD to support research in Kairos CSO Dr. Neil Bhowmick's laboratory to identify biomarkers of patients with NSCLC who have developed resistance to Osimertinib (SoC in treatment of EGFR-mutated NSCLC). This strategy will provide a means to identify patients who are most likely to benefit from ENV-105 treatment. The DoD grant underscores the validity of the underlying ENV-105 mechanism and its potential in the ongoing Phase 1 clinical study, particularly in today's challenging market environment. The company expects these additional funds to lead to more effective monitoring and early detection of drug resistance development, opening the window for more timely intervention with ENV-105, and potentially provide better patient outcomes and survival metrics. We believe this award is a sign of external validation to advance ENV-105's clinical development, and look forward to the initial Phase 1 study updates, expected by YE25. For further details on the Kairos pipeline, refer to our recent initiation report *Attacking Cancer Rx Resistance and Boosting Immune Function; Initiating at Buy and $12 PT*.

Turning back the hands of the cancer drug resistance clock with ENV-105. The goal of the ENV-105 program is reversing cancer drug resistance (i.e. those acquired through hormone therapy, radiation, I.O. etc.) by exploiting synthetic lethality, re-sensitizing patients, and enabling cancer drugs to last longer. A notable feature we highlight, is that ENV-105 adds to the treatment armamentarium by reviving the current SOC treatments (i.e. Xtandi for mCRPC and Tagrisso for EGFR-driven NSCLC) without introducing a brand-new modality per se. As a combination therapy, ENV-105 could be used to improve or extend the efficacy of such blockbuster drugs in their respective indications, providing a unique market opportunity. Here, we see ENV-105 as being leveraged by big pharma to enhance their existing oncology pipelines, providing unique partnering/collaboration opportunities. Currently, ENV-105 drug seeks to address unmet medical needs in the large markets of prostate and lung cancers. For example, the global prostate cancer therapeutics market size is valued at $12.4 billion and at $4 billion for EGFR mutant NSCLC, representing a significant opportunity for Kairos to strategically position itself.

Kairos' companion biomarker is an underappreciated strategy that could be a key to success. Another aspect of Kairos' development strategy worth highlighting with investors, in our opinion, is the inclusion of biomarker analysis in the ongoing ENV-105 clinical studies. A three-gene panel was identified to serve as a companion biomarker for patient selection, by distinguishing potential drug responsive and non-responsive patients, prior to therapy, based on the biomarker gene expression levels. Currently under co-development with the Kairos subsidiary, Enviro (acquired in 2021), we see the companion biomarker test as a significant value-add to the ENV-105 program as a means to further ensure successful clinical development and outcomes through to the NDA and FDA approval process. The biomarker test development is further supported by a $3.2 million NIH grant to Kairos CSO, Dr. Bhowmick, which will be used and verified in the ongoing multi-center randomized Phase 2 trial of ENV-105 in mCRPC as well as the randomized Phase 1 study in NSCLC. This diagnostic will seek FDA approval as a critical tool for the identification of suitable patients with mCRPC or EGFR-mutated NSCLC, guiding inclusion for treatment in Phase 3 clinical trials and strengthening an overall regulatory package as trials progress.

Valuation and Risks. We reiterate our Buy rating and $12 price target. Our valuation is based on our clinical net present value (NPV) model, which allows us to flex multiple assumptions affecting a drug's profile. We consider two key factors when considering our valuation of Kairos using our NPV approach:

- We only value ENV-105 for mCRPC for the U.S. market (20% PoS 100% contribution), which has the potential to be a blockbuster indication for Kairos. We feel we are being conservative in our market model approach of ENV-105 by only attaining ~20% market penetration and ~$700 million peak sales, while still representing an unmet medical need.
- We purposely omit the rest of Kairos' pipeline, including ENV-105 for NSCLC, which is already in the clinic. This represents a not only an additional layer of conservatism, but provides significant upside potential over the long-term by having multiple opportunities increasing the changes of potential success, in our belief.

Factors that could impede reaching our price target include failed or inconclusive clinical trials, the inability of the company to secure adequate funding to progress its drug through the development pathway or the occurrence of dilutive capital raises.

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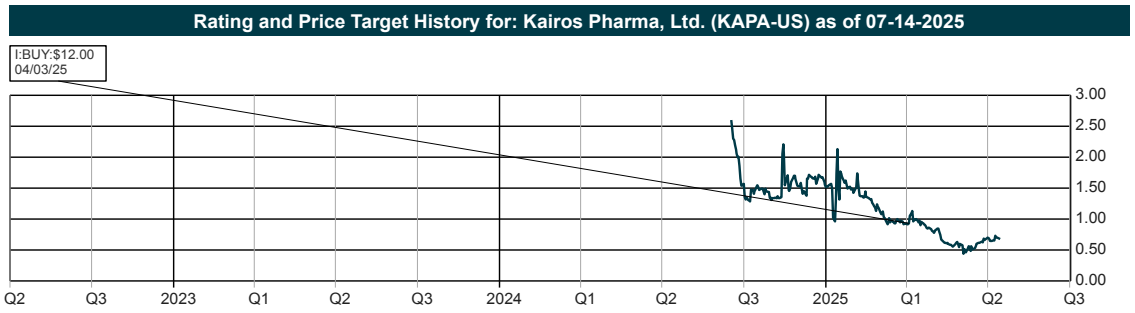

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			IB Service/Past 12 Months	
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Neutral	72	10.71%	13	18.06%
Sell	2	0.30%	0	0.00%
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