Kairos Pharma Announces FDA Clearance of Investigational New Drug (IND) for ENV105 for the Treatment of Prostate Cancer

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Phase 2 Clinical Trial to Begin in 2022 with Participation by Cedars Sinai Medical Center, University of Utah, and City of Hope

LOS ANGELES, Feb. 15, 2022 /PRNewswire/ -- Kairos Pharma, Ltd. ("Kairos"), a privately held clinical stage biotechnology company focused on drug resistance and immunotherapy for cancer, today announced that it has received FDA approval to proceed with a Phase 2 clinical trial of ENV105 with apalutamide for the treatment of metastatic castration-resistant prostate cancer. The phase II trial is sponsored by Enviro Therapeutics, a wholly-owned subsidiary of Kairos Pharma.

Kairos CEO John Yu, M.D. commented, "This IND acceptance establishes the first of many substantial clinical milestones that Kairos is working toward in 2022. We will roll out our Phase 2 clinical trial with the goal of verifying the benefit of our transformative technologies to reverse the normal course of drug resistance in patients with prostate cancer, lung cancer, and breast cancer."

ENV105 has been demonstrated to complement standard of care androgen targeted therapy with non-steroidal anti-androgens such as XTANDI® (enzalutamide) and Zytiga® (abiraterone acetate) in limiting therapeutic resistance to these drugs in a previous Phase II trial. These encouraging results is the premise for this randomized, multi-center phase II trial enrolling 100 patients. Prostate cancer patients failing to respond to androgen targeted therapy interventions will be randomized to receive the combination of ENV105 and a third-generation androgen receptor antagonist, apalutamide or apalutamide alone. Interruption of the BMP/CD105 signaling between cancer cells and surrounding non-cancer cells with ENV105 sensitizes prostate tumors to androgen targeted therapy through a novel mechanism of action. Three academic medical centers will participate in the randomized trial including Cedars Sinai Medical Center, University of Utah, and City of Hope.

Kairos Chief Scientific Officer Neil Bhowmick, Ph.D. added, "This achievement represents the next major step in testing the degree of potential clinical benefit of ENV105 for patients with androgen resistant prostate cancer."

In addition to the upcoming Phase 2 trial of ENV105 with apalutamide, a Phase 1 trial of ENV105 with Tagrisso (AstraZeneca) for lung cancer is planned to start in 2022, and a Phase 1 trial of activated T cell therapy for KROS 201 in patients with glioblastoma will enter Phase 1 clinical trials in 2022.

About Kairos Pharma

Kairos Pharma is a clinical-stage biopharmaceutical company focused on developing a diversified pipeline of cutting-edge therapeutics for cancer patients that reverse the inhibitory effects of cancer on the immune system. The Company's unique portfolio of seven drug candidates is anchored by a new class of novel drugs that reverse drug resistance and immune resistance to cancer. The Company has made unparalleled strides through its transformative technology, strong IP, and world-class team working to make a significant impact on the most pervasive problems in cancer treatment. kairospharma.com.

Forward-Looking Statements

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