Kairos Pharma Receives FDA Approval of Investigational New Drug (IND) Application for Its Phase 1 Clinical Trial of KROS 201 for the Treatment of Glioblastoma; Announces New Patent for KROS 401

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Phase 1 clinical trial of KROS 201 to begin in 2022 at Cedars Sinai Medical Center

New patent covers the method of treating fibrosis and certain forms of cancer, the composition of matter, and administering a therapy using KROS-401

LOS ANGELES, March 14, 2022 /PRNewswire/ -- Kairos Pharma, Ltd. ("Kairos"), a privately held clinical stage biotechnology company focused on drug resistance and immunotherapy for cancer, today announced that its activated T cell therapy, KROS 201, has received FDA approval to proceed with a Phase 1 clinical trial in patients with recurrent glioblastoma, a type of brain cancer. The phase I trial is sponsored by Kairos Pharma and will be conducted at Cedars Sinai Medical Center in Los Angeles.

Kairos CEO John Yu, M.D. commented, "This IND acceptance is the second substantial clinical milestone within the past month as Kairos accelerates toward its clinical goals for 2022. This first-in-man Phase 1 clinical trial will activate T cells against the cancer stem cells at the root of glioblastoma."

Kairos Chief Scientific Officer Neil Bhowmick, Ph.D. added, "This achievement pushes the envelope of immune therapies designed to target T cells against devastating cancers."

KROS 201 activated T cells (ATCs) are killer T cells that are developed in a cell culture by activating a a patient's white blood cells with cytokines or T cell activating signals and by priming dendritic cells loaded with glioblastoma cancer stem cell specific antigens. The potent activated T cells are infused intravenously into patients with recurrent glioblastoma. These cells have been shown to kill cancer stem cells, the root cause of cancer.

In addition to the upcoming Phase 1 trial of activated T cell therapy for KROS 201, a Phase 2 trial of ENV105 with apalutamide was recently granted an IND by the FDA in February. A Phase 1 trial of ENV105 with Tagrisso (AstraZeneca) for lung cancer is planned to start in 2022.

Along with this advancement of its clinical milestones, Kairos Pharma announced a notice of allowance of the United States Patent and Trademark Office of their patent Compositions and Methods for Treating Fibrosis. This patent covers the method of treating fibrosis and certain forms of cancer, the composition of matter, and administering a therapy using KROS-401, a cyclic peptide inhibitor of the IL-4 and IL-13 cytokine receptor complex. This therapeutic has been shown to treat both fibrosis and cancer by reversing the M1 to M2 immunosuppressive macrophage transition in both cancers and fibrosis.

Dr. John Yu, CEO of Kairos Pharma stated, "This milestone further supports the already substantial and diversified intellectual property portfolio of Kairos and enables the unfettered clinical development of this novel and transformative therapeutic."

Kairos VP of Research and Development Dr. Ramachandran Murali, inventor of the KROS 401 molecule, commented, "KROS-401, in addition to fibrosis and cancer, opens a new avenue in therapeutic development for neurological disorders such as Alzheimer's disease."

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.

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