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ASIA EDITION

OBI Pharma gets FDA clearance for new drug application

19 April 2018 | News

OBI-3424 is a first-in-class novel small-molecule prodrug that selectively targets cancers overexpressing the enzyme aldo-keto reductase 1C3 (AKR1C3)

OBI Pharma, Inc., a Taiwan biopharma company announced that the U.S. Food and Drug Administration (FDA) has cleared an investigational new drug (IND) application for a Phase I/II study of OBI-3424, a first-in-class DNA alkylating agent that targets cancers that overexpress the aldo-keto reductase 1C3 (AKR1C3) enzyme.

OBI plans to enroll patients with local solid tumors, including hepatocellular carcinoma (HCC) and castrate-resistant prostate cancer (CRPC).

OBI Pharma's Chief Medical Advisor, Tillman Pearce, M.D., noted, "This clinical trial intends to verify the safety and preliminary activity profile of OBI-3424, a novel first-in-class prodrug of a DNA alkylating cancer therapeutic that is selectively activated by AKR1C3, an enzyme that is overexpressed in a variety of solid and liquid tumors. We are delighted to conduct this first-in-man clinical trial at the University of Texas M.D. Anderson Cancer Center and The James Cancer Hospital and Solove Research Institute of Ohio State University, two of America's leading academic oncology research institutions."