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OBI Pharma receives FDA ODD for OBI-3424

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OBI-3424 is a first in class DNA alkylating cancer therapeutic agent targeting aldo-keto reductase 1C3 (AKR1C3) overexpressing cancers.



OBI Pharma, Inc., a Taiwan biopharma company, recently announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) for OBI-3424 for the treatment of Acute Lymphoblastic Leukemia (ALL). OBI-3424 is a first in class DNA alkylating cancer therapeutic agent targeting aldo-keto reductase 1C3 (AKR1C3) overexpressing cancers.

This is the second FDA orphan drug designation for OBI-3424. On July 9, 2018 OBI-3424 was granted orphan drug status for the treatment of Hepatocellular Carcinoma (HCC). A Phase 1/2 study of OBI-3424 in patients with solid tumors, including HCC and castrate-resistant prostate cancer (CRPC), has commenced enrollment at the University of Texas M.D. Anderson Cancer Centre.

According to Amy Huang, General Manager of OBI Pharma, this additional orphan drug designation for OBI-3424 by the FDA is a significant step in the development of this drug candidate in ALL, including T-ALL, an unmet medical need disease with limited treatment options.