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ASIA EDITION

FDA grants ODD to OBI Pharma's lead investigational drug candidate

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OBI-3424 is a first in class DNA alkylating cancer therapeutic agent for the Treatment of Hepatocellular Carcinoma (HCC)

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

A Phase 1/2 study of OBI-3424 in patients with solid tumors, including hepatocellular carcinoma (HCC) and castrate-resistant prostate cancer (CRPC), has commenced enrollment at the University of Texas M.D. Anderson Cancer centre.

Amy Huang, General Manager of OBI Pharma, noted, "The orphan drug designation for OBI-3424 by the FDA is a significant step in the development of this drug candidate. OBI-3424 is intended to treat a devastating form of Liver Cancer with limited therapeutic options. We are excited that the FDA has recognized the need to develop novel targeted therapeutic agents such as OBI-3424 in the fight against this disease."

Hepatocellular Carcinoma (HCC) is a form of liver cancer associated with various stages of malignant growth in the liver. It is the sixth most common cancer worldwide, but is rare in the United States with a prevalence of 61,483 cases in 2018. HCC is considered a lethal cancer, with a survival rate of around 12.2% for five years, and the third major leading cause of cancer-related deaths worldwide. While most liver cancers are preventable, the incidence of HCC has recently increased inthe United States, possibly due to the prevalence of common risk factors such as chronic liver disease, viral liver infections such as hepatitis, and cirrhosis. HCC patients also have a high risk of developing drug resistance to standard of care (SoC) treatments, creating a need for alternative treatment.

OBI Pharma, Inc., is a Taiwan biopharmaceutical company that was established in 2002. The company's novel first-in-class immuno-oncology portfolio against Globo Series includes: Adagloxad Simolenin (formerly OBI-822), a Globo Series active immunotherapy vaccine; OBI-888 (Globo H mAb) and OBI-999 (Globo H ADC). The company's novel first-in-class AKR1C3

targeted therapy is OBI-3424 (small-molecule prodrug) that selectively releases a potent DNA alkylating agent in the presence of the aldo-keto reductase 1C3 (AKR1C3) enzyme.