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OBI Pharma granted FDA ODD for OBI-888

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OBI Pharma, Inc., a Taiwan biopharma company, has announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for OBI-888 for the treatment of Pancreatic Cancer. OBI-888 is a first in class monoclonal antibody cancer immunotherapy targeting Globo H, a glycolipid antigen.

A Phase 1 study of OBI-888 has commenced enrollment at the University of Texas M.D. Anderson Cancer Center in patients with locally advanced or metastatic solid tumors, potentially including Pancreatic, Breast, Gastric, Esophageal, Colorectal and Lung Cancers.

Amy Huang, General Manager of OBI Pharma, noted, "The orphan drug designation for OBI-888 by the FDA is encouraging and is a significant step in the development of this novel monoclonal antibody drug candidate targeting Globo H. In addition to targeting other solid tumors, OBI-888 will be evaluated for the treatment of pancreatic cancer, a disease with very limited treatment options. OBI will continue our utmost efforts to develop innovative therapies for people living with cancer."

Pancreatic Cancer originates in the exocrine or endocrine pancreatic cells and is thought to be caused by poor diet, smoking, and genetic factors. Pancreatic Cancer is a deadly disease that currently affects 69,839 people in the US and has a survival rate of only 8.5% at five years. In addition, treatment options are limited to surgical resection for patients with early stages of the disease and these patients may only have a five-year survival rate of up to 34.3%. As Pancreatic Cancer is asymptomatic in early stages, a majority of patients are undiagnosed or misdiagnosed until advanced stages of the disease. Surgery is no longer effective at this stage of the disease, leaving a large population with limited treatment options.

OBI-888 is a novel first-in-class monoclonal antibody, which selectively targets Globo H, an antigen expressed in up to 15 epithelial cancers. This Globo H targeting antibody has been shown to induce tumor-killing via antibody dependent cell-mediated cytotoxicity (ADCC), antibody-dependent cell-mediated phagocytosis (ADCP) and complement dependent cytotoxicity (CDC).