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ASIA EDITION

FDA grants ODD to pancreatic cancer drug candidate by OBI Pharma

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First Orphan Drug Designation for OBI-999, a novel first-in-class Antibody-Drug Conjugate targeting Globo H, a glycolipid antigen found on multiple tumor types

OBI Pharma, Inc., a Taiwan biopharma company has announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) for OBI-999 for the treatment of Pancreatic Cancer. OBI-999 is a first-in-class antibody drug conjugate targeting Globo H, a glycolipid antigen.

A Phase 1/2 clinical trial of OBI-999 has commenced enrollment at the University of Texas M.D. Anderson Cancer Center, with Dr. Apostolia M. Tsimberidou as the Principal Investigator, in patients with locally advanced or metastatic solid tumors, including Pancreatic, Gastric, Colorectal and Esophageal Cancers (ClinicalTrials.gov Identifier: NCT04084366). The objective of the trial is to verify the safety and preliminary efficacy profile of OBI-999 in these patient populations.

Tillman Pearce, MD, CMO, OBI Pharma noted, "We are very excited about the potential value that OBI-999 may provide to patients with pancreatic cancer given both the high potency we have observed using OBI-999 in pancreatic cancer xenograft models and because many pancreas cancers highly overexpress Globo H, the glycolipid target of OBI-999, using the validated IHC assay that will be available for selecting patients for the Phase 2 portion of this first-in-human clinical trial."