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ASIA EDITION

BeiGene initiates clinical trial of Tislelizumab with cancer patients

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BeiGene, Ltd., a commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, today announced that the first patients have been enrolled in two global Phase 3 clinical trials of its investigational anti-PD-1 antibody, tislelizumab. These trials are evaluating tislelizumab combined with chemotherapy as potential first-line treatments in patients with locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma, and in patients with unresectable, locally advanced recurrent or metastatic esophageal squamous cell carcinoma (ESCC).

“Available data have shown promise for anti-PD-1 antibodies in patients with advanced gastric or gastroesophageal adenocarcinoma and in patients with advanced esophageal carcinoma. We are looking forward to investigating tislelizumab globally in these Phase 3 trials,” said Amy Peterson, M.D., Chief Medical Officer, Immuno-Oncology, at BeiGene. “Gastric and esophageal cancers are among the most common malignancies in Asia and collectively are responsible for over 800,000 deaths annually in China alone. We are hopeful that these global studies of tislelizumab may ultimately lead to improved treatment options for patients diagnosed with these malignancies.”

Global Phase 3 Trial in Advanced Gastric or Gastroesophageal Adenocarcinoma

The global, randomized, double-blind, placebo-controlled Phase 3 trial is designed to enroll 720 patients with locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma. Patients will either receive 200 mg of tislelizumab or placebo combined with platinum- and fluoropyrimidine-based chemotherapy, the standard chemotherapy treatment, intravenously once every three weeks.

The co-primary endpoints will be progression-free survival (PFS) and overall survival (OS). Secondary endpoints include overall response rate (ORR), duration of response (DOR) and quality of life (QoL), as well as safety and tolerability.

Global Phase 3 Trial in Advanced ESCC

The global, randomized, double-blind, placebo-controlled Phase 3 trial is designed to enroll 480 patients with unresectable, locally advanced recurrent, or metastatic ESCC. Patients will either receive 200 mg of tislelizumab or placebo combined with platinum- and fluoropyrimidine-based chemotherapy, intravenously once every three weeks.

The co-primary endpoints will be PFS and OS. Secondary endpoints include ORR, DOR, and QoL, as well as safety and tolerability.