BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Genome & Company inks clinical trial collaboration

15 January 2020 | News | By Hithaishi CB

Supply agreement with Merck KGaA, Darmstadt, Germany and Pfizer

Genome & Company, a clinical-stage biotechnology company based in Seongnam, Republic of Korea, has announced that it has entered into a clinical trial collaboration and supply agreement with Merck KGaA, Darmstadt, Germany and Pfizer Inc. to evaluate the safety, tolerability, biological and clinical activities of GEN-001 therapy in combination with avelumab, a human anti-PD-L1 therapy, in multiple cancer indications.

Under the terms of this agreement, Genome & Company will be the sponsor of the study, and Merck KGaA, Darmstadt, Germany and Pfizer will supply avelumab for the phase 1/1b clinical trial that is expected to be commenced in 2020 in the U.S. Both parties will have access to the clinical data.

The combination trial is designed to be a first-in-human (FIH) study including dose-escalation and expansion cohorts to evaluate the safety and preliminary efficacy.

"GEN-001 has been developed as the backbone of Genome & Company's immuno-oncology pipeline, and we are delighted to collaborate with the global leaders in oncology such as Merck KGaA, Darmstadt, Germany and Pfizer on this phase 1/1b clinical trial for this combination of GEN-001 and avelumab. We are excited to investigate how the preclinical data of this combination will be translated to humans. We look forward to initiating this clinical trial in the coming months," said Dr.Jisoo Pae, CEO of Genome & Company.

Avelumab Approved Indications

Avelumab (BAVENCIO®) in combination with axitinib is indicated in the US for the first-line treatment of patients with advanced renal cell carcinoma (RCC).

The US Food and Drug Administration (FDA) also granted accelerated approval for avelumab (BAVENCIO®) for the treatment of (i) adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (mMCC) and (ii) patients with locally advanced or metastatic urothelial carcinoma (mUC) who have disease progression during or following platinum-containing chemotherapy, or have disease progression within 12 months of neoadjuvant or adjuvant treatment with

platinum-containing chemotherapy. These indications are approved under accelerated approval based on tumour response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

Avelumab is currently approved for patients within 50 countries globally, with the majority of these approvals in a broad indication that is not limited to a specific line of treatment.

Avelumab Important Safety Information from the US FDA-Approved Label

The warnings and precautions for avelumab (BAVENCIO®) include immune-mediated adverse reactions (such as pneumonitis and hepatitis [including fatal cases], colitis, endocrinopathies, nephritis and renal dysfunction and other adverse reactions [which can be severe and have included fatal cases]), infusion-related reactions, hepatotoxicity, major adverse cardiovascular events (MACE) [which can be severe and have included fatal cases], and embryo-fetal toxicity.

Common adverse reactions (reported in at least 20% of patients) in patients treated with BAVENCIO® monotherapy include fatigue, musculoskeletal pain, diarrhoea, nausea, infusion-related reaction, peripheral edema, decreased appetite/hypophagia, urinary tract infection and rash. Common adverse reactions (reported in at least 20% of patients) in patients receiving BAVENCIO® in combination with axitinib include diarrhoea, fatigue, hypertension, musculoskeletal pain, nausea, mucositis, palmar-plantar erythrodysesthesia, dysphonia, decreased appetite, hypothyroidism, rash, hepatotoxicity, cough, dyspnea, abdominal pain and headache. Grade 3-4 clinical chemistry and haematology laboratory value abnormalities reported in at least 10% of patients treated with BAVENCIO® monotherapy include hyponatremia, lymphopenia, GGT increased; in patients receiving BAVENCIO® in combination with axitinib, grade 3-4 clinical chemistry and haematology laboratory value abnormalities included blood triglyceride increased and lipase increased