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First anti-cancer microbiome therapeutic receives FDA IND clearance in Asia

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Genome & Company which sponsor clinical trial of combination therapy of anti-cancer microbiome and anti-PD1/anti-PD-L1 drug receives FDA IND clearance for GEN-001

Genome & Company, a biotechnology company developing innovative therapeutics in immune-oncology, announced on 20 April 2020 that the US Food and Drug Administration (FDA) has accepted the Investigational New Drug (IND) application for GEN-001 for combination treatment with avelumab (BAVENCIO®) in patients with solid cancers. Avelumab is an anti-PD-L1 antibody co-developed and co-commercialized by Merck KGaA, Darmstadt, Germany and Pfizer Inc.

With this clearance, Genome & Company will be the first Asian company to initiate a first-in-human trial of anti-cancer microbiome and anti-PD1/anti-PD-L1 combination treatment as a sole sponsor. The phase 1/1b clinical trial will be initiated at the US clinical sites and the first patient is expected to be enrolled within this year.

"IND clearance from FDA for our first anti-cancer microbiome therapeutic GEN-001 is a very significant milestone as it will transition Genome & Company into a clinical-stage biotechnology company. We hope to add meaningful value and advancement in the microbiome and immuno-oncology industry with our combinational approach to cancer patients who have progressed on prior anti-PD1/anti-PD-L1 therapy," said Dr Hansoo Park, Chief Technical Officer of Genome & Company.

Dr Jisoo Pae, CEO of Genome & Company further quoted, "This IND approval is a meaningful corporate milestone and a critical step forward to achieving new arrangements in strategic partnering. We are indeed looking forward to further investigate how our clinical data will be translated into our cancer patients. I thank all the members and partners of Genome & Company for dedicating themselves to accomplishing this milestone."