

BioRay Announces First-Patient-In for Phase I Clinical study of BR105 in patients with advanced Malignant Tumors.

Taizhou, Zhejiang, China, July 20, 2022--BioRay Pharmaceutical Co., Ltd. (hereinafter referred to as “BioRay”) announced that the first patient with advanced malignant tumors had been dosed in the Phase I Clinical trial of self-developed Category 1 innovative drug BR105. This is an open-label, dose-escalation, and dose-expansion trial to explore the safety, tolerability, and antitumor activity of BR105. The phase Ia part of the trial aims to evaluate the safety and tolerability of BR105 monotherapy (single and multiple doses) in subjects with advanced malignancies and to explore the maximum tolerated dose (MTD). The leading entity of the clinical trial is Beijing Cancer Hospital, and the principal investigators are Prof. Jun Zhu and Prof. Lin Shen.

BR105 is a SIRP α -targeting humanized monoclonal antibody that was independently developed by BioRay, which can recognize the common variants of signal-regulated protein α (SIRP α), blocks the binding of SIRP α to CD47, disengage the “don’t eat me” signal and activate macrophages to promote phagocytosis of tumor cells.

SIRP α is a transmembrane protein expressed on the surface of myeloid cells such as macrophages, monocytes, dendritic cells, and granulocytes. The binding of SIRP α to CD47 activates phagocytosis-inhibitory signals in multiple cancer types, and tumor cells are able to evade phagocytosis by macrophages. Blocking CD47/SIRP α signaling potentiates phagocytosis of tumor cells by macrophages, and suppresses tumor growth. CD47/SIRP α can be a viable immune target for antitumor therapy.

Multiple tumor models have demonstrated the effectiveness of targeting CD47/SIRP α . Clinical studies suggest that blockage of CD47–SIRP α signaling pathway may generate antitumor activity in broad-spectrum of malignancies, including various hematologic and solid tumors. CD47/SIRP α -targeted therapy has shown positive efficacy results in acute myeloid leukemia, lymphoma, head, and neck squamous cell carcinoma, gastric cancer, and other tumors.

Unlike CD47, SIRP α has a limited tissue expression pattern. BR105 blocks CD47/SIRP α signaling pathway by targeting SIRP α , which is superior in safety. In addition, CD47 can interact with other proteins such as TSP-1 and SIRP γ , which are involved in more complex signaling pathways, and the corresponding targeted therapeutic regimens have more risk considerations to balance; therefore, developing SIRP α antibodies to block the CD47/SIRP α signaling pathway may be a more effective strategy for oncology drug development.

“CD47/SIRP α is considered one of the most prospective targets for tumor immunotherapy after PD-1/PD-L1,” said Dr. Wei Zhu, Chief Medical Officer of BioRay, “BR105 is an important candidate of our tumor immunization pipeline. We are pleased that the first patient’s dosing of BR105 has

been completed, and this marks important progress in the innovation and R&D of BioRay. We will next push forward with our research and development projects in the field of popular targets for tumor immunity and autoimmunity to benefit patients.”

ABOUT BIORAY

BioRay Pharmaceutical Co., Ltd.

BioRay is a commercial-stage biopharmaceutical company with a full suite of end-to-end capabilities in China. We focus on discovering, developing, manufacturing and commercializing medicines for immune-mediated diseases. Leveraging our expertise in immunology and diverse portfolio covering different therapeutic targets and cellular pathways, we are committed to delivering life-changing medicines and other treatment solutions for patients living with autoimmune diseases and cancer. BioRay has full-spectrum R&D expertise from drug discovery to late-stage development, industry-leading commercial-scale manufacturing and quality management systems, and a robust pipeline with more than 20 preclinical candidates and over 10 ongoing clinical projects. In addition, our well-established nationwide commercial operations support three marketed products in mainland China. Currently, we operate four R&D and manufacturing centers in Taizhou, Hangzhou and Shanghai, China and San Diego, US, and have over 1,400 employees worldwide dedicated to building a pre-eminent biopharmaceutical company by offering medicines of the highest quality while pushing the boundaries of scientific discovery.

For more information about BioRay, please visit the company website: www.bioraypharm.com/en/

CONTACT US

BD Team:

bd@bioraypharm.com

+86 021- 64185608

PR Team:

pr@bioraypharm.com

zhuoran.xu@bioraypharm.com

Media Contact:

wei.jin@bioraypharm.com