

BioRay announces IND approval for the Phase I self-developed Category 1 innovative drug BR 105 study

Taizhou, Zhejiang, China, January 12, 2022 -- BioRay Pharmaceutical Co., Ltd. (hereinafter referred to as BioRay) announced that the National Medical Products Administration (NMPA) has approved the Investigational New Drug (IND) application for the self-developed Category 1 innovative drug BR105 for oncology treatment. As a novel agent for anti-tumor immunotherapy, BR105 is a SIRP α -targeting humanized monoclonal antibody that was independently developed by BioRay, which can recognize 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. CD47 is the major ligand of SIRP α , which is widely expressed on the surfaces of normal cells. As one of the important mechanisms of tumor evasion from immune surveillance, CD47/SIRP α signaling is closely related to tumor progression and metastasis. The SIRP α -CD47 interaction transmits a ‘do not eat me’ signal for immune evasion and prevents the phagocytosis of tumor cells by macrophages. Therefore, targeting CD47/SIRP α has become a promising strategy to promote anti-tumor immunotherapy. Clinical studies suggest that blockage of the CD47–SIRP α signaling pathway has shown the positive efficacy results in acute myeloid leukemia, lymphoma, head and neck squamous cell carcinoma, gastric cancer, and other tumors.

SIRP α has the potential to be used in combination with T-cell immune checkpoint inhibitors such as anti-PD-1 antibodies and anti-PD-L1 antibodies, which is expected to solve the problems of drug resistance and non-response faced by PD-1/PD-L1 inhibitors in clinical practice. BR105 inhibits the CD47/SIRP α signaling pathway by targeting SIRP α , which avoids the hematologic toxicity by targeting CD47 and is superior in safety. Targeting SIRP α could activate innate immune responses by activating myeloid cells. On the other hand, BR105 plays a synergistic role with antibodies targeting tumor-associated (TAA) antigens to further enhance the tumor-killing effect of TAA antibody-mediated immune cells.

In preclinical studies, BR105 was able to bind to different variants of SIRP α and block the SIRP α -CD47 interaction. The in vitro and in vivo efficacy of BR105 showed that it could effectively relieve CD47/SIRP α -mediated phagocytosis inhibition signal and promote anti-tumor immune response; moreover, BR105 did not affect the T cell activation signal involved in SIRP γ . Meanwhile, in toxicological studies, BR105 did not cause hematological toxicity and showed excellent safety.

CD47/SIRP α is considered one of the most prospective targets for tumor immunotherapy after PD-1/PD-L1. There is no monoclonal antibody targeting SIRP α in the worldwide market up to now. Dr. Haibin Wang, Chief Executive Officer of BioRay, said, "The approval of BR105 injection in clinical trials will further enrich BioRay's product pipeline and demonstrates BioRay's determination to

provide a comprehensive and diverse product portfolio for oncology patients. We are in the process of laying out the next-generation targets, and our research and development programs in the areas of popular tumor immune targets and autoimmunity are progressing steadily. We will make every effort to advance the clinical trials of BR105 and expect that it will be approved for marketing as soon as possible to benefit the majority of oncology 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