

BioRay Filed IND Application for BRY812, a Novel Antibody Drug Conjugate Targeting LIV-1

Shanghai, China, May 24, 2023 /PRNewswire/--BioRay Pharmaceutical Co., Ltd. (hereinafter referred to as BioRay) announced that the Investigational New Drug (IND) application for the clinical trial of its proprietary BRY812, **a novel antibody-drug conjugate (ADC) targeting human LIV-1 for the treatment of advanced malignant tumors**, has been accepted by the China National Medical Products Administration (NMPA) (Acceptance No. CXSL2300366).

LIV-1, also known as SLC39A6 or ZIP6, is a multi-pass transmembrane protein with zinc transporter and metalloproteinase activity. Its involvement in the homeostatic metabolism of zinc in cells and its role in promoting cell growth make it a key factor in tumor metastasis and the epithelial-mesenchymal transformation (EMT) process.

BRY812 is a LIV-1 targeting ADC developed on BioRay's CysLink™ technology platform where highly stable conjugation is created through irreversible chemistry. By binding to LIV-1 on the surface of tumor cells, the ADC-target complex enters the tumor cell's lysosome through endocytosis, releasing small molecule toxins that selectively kill tumor cells. In pre-clinical pharmacological studies, **BRY812 demonstrated significant antitumor activity in various tumor models. Compared to other ADCs targeting the same pathway, BRY812 has higher stability in circulation by eliminating payload exchange, delivering toxins more selectively to tumor tissue, which resulted in a superior safety profile in pre-clinical toxicology studies.** Globally, no LIV-1 targeting ADC has received marketing approval yet, and BioRay's BRY812 is anticipated to be the second LIV-1 ADC that reaches the clinical stage.

Dr. Haibin Wang, CEO of BioRay, stated, "Since this January, we have obtained the IND approval of two innovative antibody drug candidates, BR108 and BRY805. We are committed to finding better therapeutic options for patients living with cancers and immune-mediated diseases. We will continue the research in exploring innovative targets, technologies, and therapeutic modalities, including ADCs.

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:

shenmin.bi@bioraypharm.com