

BioRay Announces First-Patient-In for Phase II Clinical study of Zuberitamab in Patients with Primary immunologic thrombocytopenic purpura

Taizhou, Zhejiang, China, December 2, 2021--BioRay Pharmaceutical Co., Ltd. (hereinafter referred to as “BioRay”) announced that the first patient with Primary immunologic thrombocytopenic purpura (ITP) had been dosed in the Phase II Clinical trial of self-developed Zuberitamab (development code: HS006). The study aims to evaluate the safety and efficacy of Zuberitamab (HS006) in subjects with primary persistent or chronic ITP who failed from prior therapy(ies). The leading entity of the clinical trial is Tongji Medical College, Union Hospital, Huazhong University of Science and Technology and the principal investigator is Prof. Yu Hu.

Zuberitamab (HS006) is a human-mouse chimeric monoclonal antibody that specifically binds to B-lymphocyte antigen CD20 and can kill B cells via ADCC and CDC action. Zuberitamab (HS006) has demonstrated a favorable safety and efficacy profile in B-cell lymphoma in clinical trials. As B cells play an important role in the pathogenesis of autoimmune diseases such as primary immunologic thrombocytopenic purpura (ITP), rheumatoid arthritis (RA), and multiple sclerosis (MS), Zuberitamab (HS006) has the potential to be used in the treatment of autoimmune diseases.

Primary immunologic thrombocytopenic purpura (ITP) is an acquired autoimmune disease characterized by thrombocytopenia. The pathogenesis of ITP is mainly due to the loss of immune tolerance to the patient's platelet membrane antigens. The patient's B cells produce antibodies against different platelet antigens, leading to the formation of antigen-antibody complexes, and resulting in excessive destruction of platelets in the spleen or liver. Meanwhile, thrombopoiesis is impaired. Zuberitamab (HS006) specifically clears B-lymphocytes, thereby reducing autoantibody production and platelet destruction. Zuberitamab (HS006) is expected to bring an alternative treatment option for ITP patient and improve their quality of life.

“Zuberitamab (HS006) is a self-developed monoclonal antibody that targets the CD20 protein on the surface of B cells. It can rapidly, thoroughly and durably remove CD20+ B cells, and this effect is reversible after drug withdrawal,” said by Dr. Haibin Wang, the Chief Medical Officer (CEO) of BioRay, “The Phase III Clinical trial of Zuberitamab (HS006) for primary treatment of diffuse large B-cell lymphoma has completed the observation of the primary endpoint, and the study results confirmed its good safety, tolerability and efficacy, which provides strong support for the subsequent clinical development of ITP. Based on the existing achievements, BioRay will make every effort to promote its clinical research in ITP and other diseases and promote the early launch of this product in China to benefit more 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/

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