The New Drug Application of BioRay's Zuberitamab Injection has been accepted by China's National Medical Products Administration

Taizhou, Zhejiang, China, January 7, 2022 -- BioRay Pharmaceutical Co., Ltd. (hereinafter referred to as "BioRay") announced that China's National Medical Products Administration (NMPA) had accepted the New Drug Application (NDA) for the self-developed Category 1 innovative drug Zuberitamab (R&D Code: HS006, Trade name: Anruixi) for the first-line treatment of CD20 Positive Non-Hodgkin lymphoma (Acceptance No. CXSS2200001). It is not only BioRay's first New Drug Application of Category 1 innovative drug accepted by NMPA but also the fifth drug of BioRay for commercialization after the launch of Anbainuo®, Anjianning®, Anbaite®, and Anshuzheng®.

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. As a Category 1 therapeutic drug, Zuberitamab injection hasn't been commercialized domestically and internationally. The indication of the application is Diffuse large B-cell lymphoma (DLBCL). DLBCL is a type of malignant tumor with striking heterogeneity originating from B-lymphocytes. The disease grows diffusely. The nucleus of cancer cells is similar to or even larger than the normal tissue cells, which is usually two times larger than normal lymphocytes. DLBCL is the most common type of non-Hodgkin lymphoma (NHL) worldwide, accounting for 30% to 40% of NHL cases in all regions. In China, DLBCL accounts for 40.8% of all cases of NHL.

Zuberitamab has different Amino Acid Sequences, and binds to different CD20 epitopes compare to MabThera®. In the studies of in vitro biological activity, Zuberitamab showed stronger ADCC activity. Likewise, in human pharmacokinetic studies, Zuberitamab demonstrated a larger volume of distribution at steady-state and lower serum drug concentrations. In pharmacodynamic studies, Zuberitamab exhibited more sustained clearance of B cells and more sustained activation of CD3+/CD8+ T cells. To clarify the curative effect of the initial treatment of DLBCL with Zuberitamab. BioRay has conducted a phase 3, multi-center, randomized, non-inferiority trial (REFLECT) in China, six cycles of Zuberitamab+CHOP or Rituximab +CHOP were applied, and the primary endpoint was ORR after 6 treatment cycles, the secondary endpoints were CRR after 6 treatment cycles, and the DOR, PFS, EFS, OS in 1-3years. The trial achieved the primary endpoint, and the Zuberitamab group showed a superior trend over the control group in long-term efficacy.

Dr. Haibin Wang, the Chief Medical Officer (CEO) of BioRay, said: "Currently, BioRay has more than ten products in the clinical research stage, four of which have been commercialized. Zuberitamab is the first Category 1 innovative drug and the fifth product of BioRay that has applied for marketing approval.

The New Drug Application of Zuberitamab is a landmark achievement for the academician Beifen Shen's team from the Chinese Academy of Engineering about the years of research on

industrialization and transformation. We appreciate the outstanding contribution made by academician Shen's team in the field of monoclonal antibodies. It laid a solid foundation for the significant clinical value of Zuberitamab. We are also grateful to the Professor Wenqi Jiang of the Cancer Prevention and Control Center of Sun Yat-sen University, Professor Zhu Jun of Peking University Cancer Hospital, and other 40+ hospitals and researchers who have greatly contributed to promoting clinical research of Zuberitamab.

We are delighted to achieve this significant milestone, representing a remarkable breakthrough in the innovative research of BioRay. I expect Zuberitamab can be approved as soon as possible to bring better treatment options for lymphoma patients in China."

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@biorayphar m.com