

Zuberitamab Injection (Anruixi®), BioRay's first self-developed CD20-targeted Type 1 innovative biological product, has been successfully included in the National Medical Insurance Drug List 2023

On December 13, BioRay Biopharmaceutical Co., Ltd. (hereinafter referred to as "BioRay") announced that Zuberitamab Injection (trade name: Anruixi®), its first self-developed and produced type 1 anti-CD20 innovative biological product, has been successfully included in the National Basic Medical Insurance, Work Injury Insurance, and Maternity Insurance Drug List (2023) (hereinafter referred to as the "National Medical Insurance List"), with the medical insurance coverage extending to CD20-positive diffuse large B-cell lymphoma and DLBCL, NOS adult patients, when treated in combination with standard CHOP chemotherapy. The new medical insurance list will officially take effect on January 1, 2024.

Zuberitamab Injection Anruixi® was approved for marketing in China in May 2023. It is a novel monoclonal antibody that specifically targets the CD20 antigen on the surface of B cells to exhibit anti-tumor effects. CD20-targeted drugs are indicated for not only malignancies originating from B cells, but also autoimmune diseases such as multiple sclerosis and rheumatoid arthritis.

Before Zuberitamab Injection Anruixi® was included in the medical insurance, BioRay had already entered into a patient assistance program with relevant public welfare foundations, with the purpose of providing support to eligible patients and alleviating their financial burden associated with medication. The addition of Anruixi® in the National Medical Insurance List not only introduces a new treatment option for domestic lymphoma patients but also ensures sustained accessibility and affordability for patients. While offering superior treatment options, it improves the long-term health gains for patients, thereby making a valuable contribution to both families and society.

The data indicates that diffuse large B-cell lymphoma is the most common type of non-Hodgkin lymphoma, with an annual increase of 26,000 adult DLBCL patients. It stands as the most common form of adult non-Hodgkin's lymphomas globally, constituting 30% to 40% of all cases across regions. Currently, although 50% to 60% of DLBCL patients attain complete remission in their initial treatment, the incidence and mortality of B-cell lymphomas are still increasing annually. Approximately 30% to 40% of patients are developing into relapsed/refractory types after initial standard treatment. As BioRay's first Type 1 innovative biological product on the market, Zuberitamab demonstrates a stronger antibody-dependent cell-mediated cytotoxicity (ADCC) compared to other anti-CD20 monoclonal antibody products. It also features a larger steady-state volume of distribution, enabling a more persistent clearance effect on B cells and thus enhancing therapeutic efficacy.

In the future, BioRay will further expand its research on new indications for Zuberitamab, including the development of related indications for other subtypes of B-cell lymphomas, as well as for primary immune thrombocytopenia (ITP), rheumatoid arthritis (RA), and nephrology to ensure that Zuberitamab meets the evolving needs of a broader spectrum of clinical patients.

Dr. Wang Haibin, CEO of BioRay, stated, "We express our sincere gratitude to the National



Healthcare Security Administration for including Zuberitamab Injection Anruixi®, which received approval for market release this year, in the National Medical Insurance List. As BioRay's first Type 1 innovative biological product, Anruixi® demonstrates the ability to clear B cells more swiftly and persistently, thus effectively reducing the risk of mortality. The evaluation methods and specific rules for this year's revision of the National Medical Insurance List have been further refined and improved. This year's catalog features the highest number of product varieties ever, among which oncology medications have been a perennial focal point in the market. The inclusion of Zuberitamab Injection Anruixi® in the National Medical Insurance List will offer a novel domestic option to a broader spectrum of lymphoma patients, thereby supporting BioRay's independent innovations in breaking new ground in the field of oncology drugs. Moving forward, BioRay will continue to uphold the mission of enhancing the breadth and depth of life, working toward the rapid scalability of Zuberitamab Injection Anruixi® to benefit a greater number of patients and families."

ABOUT BIORAY

BioRay is a pioneer in China's biopharmaceutical industry focusing on immune-mediated diseases. Its extensive autoimmune and oncology portfolio includes six marketed products and over 10 clinical-stage drug candidates. Operating a fully integrated platform with end-to-end capabilities across drug discovery, clinical development, manufacturing, and commercialization, BioRay has over 1,700 employees globally, with main sites in Taizhou, Hangzhou, Shanghai, and San Diego.

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