Junshi Biosciences Announces Acceptance of the NDA for Roconkibart (IL-17A) for the Treatment of Moderate to Severe Plaque Psoriasis

SHANGHAI, China, Dec 5, 2025 -- Shanghai Junshi Biosciences Co., Ltd (Junshi Biosciences, HKEX: 1877; SSE: 688180), a leading innovation-driven biopharmaceutical company dedicated to the discovery, development, and commercialization of novel therapies, announced that the new drug application ("NDA") for the company's product, roconkibart injection (a recombinant humanized anti-IL-17A monoclonal antibody injection, product code: JS005), for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy has been accepted by the National Medical Products Administration ("NMPA").

Psoriasis is a common chronic, recurrent, inflammatory, and systemic disease mediated by the immune system. According to the Guideline for the Diagnosis and Treatment of Psoriasis in China (2023 edition), the prevalence of psoriasis in China reached 0.47% in 2008, significantly higher than the 0.12% recorded in 1984. Psoriasis can be accompanied by other systemic abnormalities, patients with moderate-to-severe psoriasis have an increased risk of developing metabolic syndrome and atherosclerotic cardiovascular disease. Mental health conditions such as depression, anxiety, and suicidal tendencies caused by physical and psychological distress are also relatively common among the patients with psoriasis. Therefore, psoriasis is a disease that seriously affects the physical and mental health of patients.

The NDA is mainly based on the multi-center, randomized, double-blind, parallel and placebo-controlled pivotal registrational phase 3 clinical study (study number: JS005-005-III-PsO). Led by Professor Jianzhong ZHANG from the Peking University People's Hospital, the study was conducted in 60 clinical sites across China, and a total of 747 patients with moderate to severe plaque psoriasis were enrolled.

The study results showed that, treatment for 12 weeks with roconkibart significantly improved the Psoriasis Area and Severity Index (PASI) of 75/90/100 and the static Physician Global Assessment (sPGA) score of 0 or 1. The efficacy was significantly superior to that of the placebo group and remained stable throughout the 52-week treatment, with an overall favorable safety profile. The relevant study results will be announced at future international academic conferences.

Prof. Jianzhong ZHANG from the Peking University People's Hospital said, "Roconkibart, as a highly selective monoclonal antibody targeting IL-17A, acts directly on the core inflammatory pathway of psoriasis. Pivotal Phase 3 clinical data confirm that roconkibart achieves rapid and profound clearance of psoriatic lesions while demonstrating a favorable safety profile, offering a new clinical treatment option that balances efficacy and safety. The acceptance of this NDA marks a critical step in transitioning this therapy from clinical research to real-world practice. We anticipate its early approval to provide a significant new treatment choice for adults in China with moderate-to-severe plaque psoriasis, which will further enrich and optimize current clinical strategies."

Dr. Jianjun ZOU, General Manager and CEO of Junshi Biosciences, said, "The acceptance of the NDA by the NMPA for roconkibart in the treatment of moderate-to-severe plaque psoriasis marks a significant milestone in advancing our autoimmune disease pipeline. As the first innovative achievement in this core therapeutic area, roconkibart demonstrates our technological expertise and R&D capabilities in biologic

innovation. We will actively collaborate with regulatory authorities during the review process, spare no effort to advance the product's market approval, and strive to bring this new therapeutic option to patients at the earliest opportunity—fulfilling our patient-centric commitment."

About Roconkibart Injection

JS005 is a specific anti-IL-17A monoclonal antibody independently developed by Junshi Biosciences. IL (interleukin)-17A is a pleiotropic cytokine, and the disordered secretion of which is closely related to the occurrence and progression of autoimmune diseases such as psoriasis, rheumatoid arthritis and ankylosing spondylitis. By binding to IL-17A with high affinity and selectively blocking the binding of IL-17A with its receptor IL-17RA/IL-17RC, JS005 blocks the activation of downstream signaling pathways and the release of inflammatory factors, thereby effectively alleviating the symptoms of autoimmune diseases. So far, the NDA for roconkibart for the treatment of moderate to severe plaque psoriasis has been accepted by the NMPA. All subjects in the phase 2 clinical study of roconkibart for the treatment of active ankylosing spondylitis have completed the treatment and entered the safe follow-up period.

About Junshi Biosciences

Founded in December 2012, Junshi Biosciences (HKEX: 1877; SSE: 688180) is an innovation-driven biopharmaceutical company dedicated to the discovery, development and commercialization of innovative therapeutics. The company has established a diversified R&D pipeline comprising over 50 drug candidates, with five therapeutic focus areas covering cancer, autoimmune, metabolic, neurological, and infectious diseases. Five of the company's products have received approvals in China and international markets, one of which is toripalimab, China's first domestically produced and independently developed anti-PD-1 monoclonal antibody. Toripalimab has been approved in over 40 countries and regions including China, the US, and Europe. During the COVID-19 pandemic, Junshi Biosciences actively shouldered the social responsibilities of a Chinese pharmaceutical company through its involvement in developing etesevimab, MINDEWEI®, and other novel therapies for the prevention and treatment of COVID-19.

With a mission of "providing patients with world-class, trustworthy, affordable, and innovative drugs," Junshi Biosciences is "In China, For Global." At present, the company boasts approximately 2,500 employees in the United States (Maryland) and China (Shanghai, Suzhou, Beijing, Guangzhou, etc.). For more information, please visit: http://www.junshipharma.com.

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