Junshi Biosciences Announces the Phase 3 Study of JS005 (IL-17A) for the Treatment of Moderate to Severe Plaque Psoriasis Met Primary Endpoints

SHANGHAI, China, Aug 8, 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 company's product, recombinant humanized anti-IL-17A monoclonal antibody (code: JS005) has achieved positive results in a multi-center, randomized, double-blind, parallel, placebo-controlled pivotal registrational Phase 3 clinical study (study number: JS005-005-III-PsO) for the treatment of moderate to severe plaque psoriasis. Both the co-primary endpoints and key secondary endpoints showed statistically significant and clinically meaningful improvements. Junshi Biosciences plans to submit the new drug application of this product to the regulatory authorities in the near future.

Psoriasis is a common chronic, recurrent, inflammatory, and systemic disease mediated by the immune system. Its prevalence varies significantly across different regions: the overall global prevalence of psoriasis ranges from 2.0% to 3.0%, while in China it is 0.47%. According to data released by the World Psoriasis Day Consortium, the total number of patients with psoriasis worldwide is approximately 125 million, and shows a year-on-year increasing trend. 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, and is also a global disease that urgently needs to be addressed.

So far, the multi-center, randomized, double-blind, parallel, placebo-controlled pivotal registrational Phase 3 study (study number: JS005-005-III-PsO) of JS005 has been successfully completed and met the co-primary endpoints and key secondary endpoints. Led by Professor Jianzhong ZHANG from the Peking University People's Hospital, the study was conducted in 60 clinical sites across China, and its primary objective is to determine whether the proportion of participants achieving at least a 90% improvement in Psoriasis Area and Severity Index (PASI 90) and a static Physician Global Assessment (the "sPGA") score of 0 or 1 at Week 12 in JS005 group are both superior to that of the placebo group.

The study results showed that, compared to the placebo, JS005 significantly improved the area and severity of psoriasis lesion in participants, and the proportion of participants achieving a sPGA score of 0 or 1 was also significantly higher, and JS005 demonstrated good safety in participants with moderate to severe plaque psoriasis. The relevant study results will be announced at future international academic conferences.

Prof. Jianzhong ZHANG from the Peking University People's Hospital said, "Patients with moderate-to-severe psoriasis suffer from long-term recurrent skin lesions and pruritus, imposing significant physical and mental burdens. Traditional treatments remain limited, making the success of this Phase 3 study for JS005 a significant milestone. Results demonstrate JS005's superior efficacy in achieving deep symptom remission, sustained therapeutic effects, and improved quality of life. We hope this therapy will soon benefit millions of patients, further advancing China's psoriasis treatment landscape."

Dr. Jianjun ZOU, General Manager and CEO of Junshi Biosciences, said, “We sincerely thank patients, investigators, and the R&D team for their exceptional contributions in achieving the primary endpoints of JS005's Phase 3 study. This milestone not only brings new hope to patients with moderate-to-severe psoriasis but also marks our innovation breakthrough in the autoimmune field. Moving forward, we will actively collaborate with regulators to accelerate the availability of this innovative therapy, ensuring earlier patient access.”

About JS005

JS005 is an 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 phase 3 clinical study of JS005 for the treatment of moderate to severe plaque psoriasis has met the co-primary endpoints and key secondary endpoints. All subjects in the phase 2 clinical study of JS005 for the treatment of active ankylosing spondylitis have completed the primary endpoint visit and entered the extension treatment 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 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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