Junshi Biosciences Announces Completion of First Patient Dosing in the Phase 3 Clinical Trial of JS203 in Combination with Chemotherapy for the Treatment of Diffuse Large B-cell Lymphoma

SHANGHAI, China, October 23, 2026 (GLOBE NEWSWIRE) -- 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 first patient dosing has been completed in a randomized, open-label, multicenter phase 3 clinical study of the company's product, a recombinant humanized anti-CD20/CD3 bispecific antibody (code: JS203), in combination with chemotherapy compared to rituximab in combination with chemotherapy in patients with relapsed/refractory diffuse large B-cell lymphoma (R/R DLBCL) (the JS203-003-III-DLBCL Study; NCT07808827). This study is the first registrational clinical study for JS203.

DLBCL is one of the most common types of non-Hodgkin lymphoma (NHL), accounting for approximately 40% of adult NHL cases in China. According to GLOBOCAN 2022 statistics, there are approximately 45,000 new cases of DLBCL in China each year, and the incidence rate shows a slow increasing trend. DLBCL is characterized by high aggressiveness and rapid progression. A retrospective study in an Asian population showed that, even after active treatment, patients with relapsed or refractory DLBCL had a median overall survival (mOS) of over one year and a 5-year survival rate of approximately 30%, which necessitates the exploration of more proactive and effective treatment options.

JS203 is a recombinant humanized anti-CD20/CD3 bispecific antibody self-developed by Junshi Biosciences. It consists of anti-CD20 segment and anti-CD3 segment. By associating and activating lymphoma cells (binding to CD20) and T cells (binding to CD3), JS203 can enable T cells to kill lymphoma cells effectively.

Results from a phase 1 clinical study showed that, for JS203 monotherapy at the recommended phase 2 dose (RP2D) administered with step-up dosing (SUD) to 30 mg for the treatment of patients with CD20-positive relapsed or refractory B-cell non-Hodgkin lymphoma, the objective response rate (ORR) reached 72.4%. Among patients with DLBCL, the ORR was 69.7%, and the complete response rate CRR was 39.4%, with persistent relief observed. Meanwhile, the overall safety profile was manageable, with a cytokine release syndrome (CRS) incidence rate of only 27.3% and no occurrence of immune effector cell-associated neurotoxicity syndrome (ICANS).

The JS203-003-III-DLBCL Study is a randomized, open-label, multicenter phase 3 clinical trial, with Professor Yuqin SONG of Beijing Cancer Hospital serving as the principal investigator. It aims to compare the efficacy and safety of JS203 in combination with chemotherapy compared to rituximab in combination with chemotherapy in patients with relapsed or refractory diffuse large B-cell lymphoma. The study plans to enroll 282 subjects, with overall survival (OS) as its primary endpoint. This study is the first registrational clinical study for JS203.

The JS203-003-III-DLBCL study team commented: “Early clinical studies have shown encouraging efficacy and a favorable safety profile for JS203 in combination with chemotherapy in patients with R/R DLBCL, reinforcing our confidence in the ongoing Phase 3 study. We are committed to advancing the study with rigor and efficiency, with the aim of making a new treatment option available to patients as soon as possible.”

About JS203

JS203 is a recombinant humanized anti-CD20/CD3 bispecific antibody self-developed by Junshi Biosciences. CD20 is a B lymphocyte restricted differentiation antigen and one of the most successful targets for B-cell lymphoma treatment. CD3 is an important marker on the surface of T cells, and the main mechanism of T cell engaging bispecific antibodies is using CD3 as a mediator to activate T cells to specifically attack tumor cells. JS203 consists of anti-CD20 segment and anti-CD3 segment. By associating and activating lymphoma cells (binding to CD20) and T cells (binding to CD3), JS203 can enable T cells to kill lymphoma cells effectively. To date, a Phase 3 clinical study evaluating JS203 in combination with chemotherapy versus rituximab in combination with chemotherapy in patients with relapsed or refractory diffuse large B-cell lymphoma (R/R DLBCL) is ongoing.

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. With our outstanding capacity for innovative drug discovery, strong biotechnology R&D capability, and large-scale production capacity, we have successfully developed a drug candidate portfolio with global competitiveness and a well-structured research pipeline, which covers therapeutic areas including cancer, autoimmune, metabolic, and infectious diseases. Our innovative field spans cutting-edge therapeutic modalities, including mAbs, small-molecule drugs, ADCs, bsAb/msAb, fusion proteins, nucleic acid drugs and vaccines. Five of the company’s products have received marketing authorizations in China and international markets, one of which is toripalimab, China’s domestically developed anti-PD-1 monoclonal antibody. Toripalimab has been approved in over 50 countries and regions including China, the US, and Europe.

With a mission of “providing patients with world-class, trustworthy, affordable, and innovative drugs,” Junshi Biosciences is “In China, For Global.” The company currently employs more than 3,000 people worldwide. Headquartered in Shanghai, China, it has a business presence in multiple countries and regions around the world. For more information, please visit: http://www.junshipharma.com.

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