Junshi Biosciences Presents 11 Clinical Trials of Toripalimab at the ESMO Congress 2023

SHANGHAI, China, 27, 2023 (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 the presentation of new clinical trial results at the European Society of Oncologists ("ESMO") Immuno-Oncology Congress 2023, an international conference held in Madrid, Spain, from October 20th to 24th. At the ESMO Congress 2023, Junshi Bioscience showcased a total of 11 clinical trials involving the groundbreaking immune-oncology drug, toripalimab (anti-PD-1 monoclonal antibody), in the forms of 1 late-breaking abstract, 2 proffered paper oral presentations, and 8 posters. These trials encompass ten diverse fields, including lung cancer, kidney cancer, head and neck cancer, breast cancer, colorectal cancer, cervical cancer, thymus cancer, and lymphoma.

"This year's ESMO Congress highlighted the most recent results from 11 clinical studies conducted with our core product, toripalimab," said Dr. Jianjun ZOU, Global Research and Development President of Junshi Biosciences. "Among these studies, the results of EXTENTORCH study involving small cell lung cancer and the RENOTORCH study focusing on renal cell carcinoma were presented for the first time. As 'PD-1+X' combination therapy achieves further clinical advancement across multiple indications, it will further bolster Junshi Biosciences' extensive immuno-oncology pipeline, one that has been cultivated through many years of dedication."

The RENOTORCH Study: Median PFS reaches 18.0 months! Record-setting results for 1st line immunotherapy in advanced kidney cancer

Led by Professor Jun GUO of Beijing Cancer Hospital and Professor Yiran HUANG of Renji Hospital affiliated with Shanghai Jiao Tong University School of Medicine, RENOTORCH is China's first phase III clinical study to focus on immunotherapy for advanced renal cell carcinoma. Study findings were unveiled for the first time during a proffered paper session at the ESMO Congress. Professor Xinan SHENG of Beijing Cancer Hospital gave a comprehensive overview of the research results in the oral presentation. The full manuscript of the study has also been published in *Annals of Oncology* (Impact factor 51.8) on the day of presentation.

The RENOTORCH study (NCT04394975) is a randomized, open-label, multicenter phase III clinical study that enrolled 421 patients from 47 medical centers with intermediate to high-risk unresectable or metastatic renal cell carcinoma (RCC) who had received no prior systematic treatment. RENOTORCH is the first pivotal phase III study of immunotherapy for advanced RCC in China.

As of March 31, 2023 (median follow-up time of 14.6 months), the RENOTORCH interim analysis results demonstrated that when compared to sunitinib monotherapy, toripalimab combined with axitinib significantly improved the patients' progression-free survival (PFS) and objective response rate (ORR) while maintaining a manageable safety profile.

According to assessments by the independent review committee (IRC), the median PFS was 18.0 months in the toripalimab-axitinib group, nearly double that of the sunitinib group, which had a median PFS of

9.8 months. Toripalimab plus axitinib reduced the risk of disease progression or death by 35% (HR=0.65; 95% CI: 0.49-0.86; P=0.0028) compared to sunitinib. The 1-year and 2-year PFS rates of these two groups were 62.7% vs. 45.4% and 44.6% vs. 30.2%, respectively. Notably, unlike previous studies of a similar nature that included patients across all risk levels, this study only enrolled patients at intermediate to high risk and yet still achieved the longest median PFS ever reported in 1st line RCC.

When compared to patients in the sunitinib group, toripalimab-axitinib provided a superior ORR (IRC-assessed ORR of 56.7% vs. 30.8%, P<0.001) and a prolonged duration of response (DoR) (median DoR not yet reached vs. 16.7 months; HR=0.614; 95% CI: 0.340-1.137).

At the interim analysis, an OS trend favoring the toripalimab plus axitinib combination over sunitinib monotherapy (median OS not yet reached vs. 26.8 months) has also been demonstrated, with a 39% lower risk of death (HR=0.61; 95% CI: 0.40-0.92). The 1-year and 2-year OS rates of the toripalimab-axitinib group and sunitinib group were 90.5% vs. 81.9% and 71.8% vs. 63.2%, respectively.

The combination had a manageable safety profile and no new safety signals were identified.

In July 2023, based on RENOTORCH's promising results, the National Medical Products Administration (NMPA) formally accepted the supplemental new drug application for toripalimab plus axitinib as the first-line treatment for patients with unresectable or metastatic RCC.

The EXTENTORCH Study: World's 1st PD-1 inhibitor to achieve both positive PFS and OS results in phase III SCLC study

EXTENTORCH, a phase III study of toripalimab combined with chemotherapy as first-line treatment of extensive-stage small cell lung cancer (ES-SCLC), made its debut as a late-breaking abstract at the ESMO Congress 2023. The study was led by principal investigator Professor Ying CHENG of Jilin Cancer Hospital, and presented by Professor Ying LIU from Jilin Cancer Hospital at the ESMO Congress.

The EXTENTORCH study (NCT04012606) is a randomized, double-blind, placebo-controlled, multicenter phase III clinical study designed to compare the efficacy and safety of toripalimab vs. placebo in combination with etoposide plus platinum for the first-line treatment of ES-SCLC. EXTENTORCH enrolled a total of 442 ES-SCLC patients who had received no prior systematic treatment from 51 medical centers in China. In May 2023, EXTENTORCH successfully reached its primary endpoints, and toripalimab became the world's first PD-1 inhibitor to achieve two primary endpoints, OS and PFS, in a phase III study of first-line treatment for ES-SCLC.

The findings from the EXTENTORCH study revealed that compared to chemotherapy alone, toripalimab plus chemotherapy for the first-line treatment of patients with ES-SCLC, coupled with toripalimab monotherapy as maintenance therapy, significantly prolonged PFS and OS while maintaining a manageable safety profile. With these promising results, toripalimab combined with chemotherapy is poised to become a standard first-line therapy for ES-SCLC.

The final PFS analysis (median follow-up time of 11.8 months) demonstrated that compared to chemotherapy alone, toripalimab combined with chemotherapy significantly improved patients' PFS (researcher-assessed median PFS of 5.8 vs. 5.6 months) while reducing the risk of disease progression or

death by 33% (HR=0.667; 95% CI: 0.539-0.824; P=0.0002).

Biomarker analyses revealed that both PFS and OS improved in the toripalimab-chemotherapy group, regardless of the patients' tumor mutational burden (TMB) status. Additionally, mutations in focal adhesion/integrin pathway were associated with poorer PFS and OS prognoses in patients receiving toripalimab plus chemotherapy.

In terms of safety, toripalimab combined with chemotherapy has a manageable safety profile and no new safety signals were identified.

In July 2023, based on the EXTENTORCH trial results, the NMPA accepted the supplemental new drug application for toripalimab plus etoposide and platinum as the first-line treatment of ES-SCLC.

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. Four of the company's innovations have already reached the Chinese or international markets, one of which is China's first self-developed anti-PD-1 monoclonal antibody, toripalimab. Additionally, more than 30 drugs are currently in clinical development. 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 3,000 employees in the United States (San Francisco and Maryland) and China (Shanghai, Suzhou, Beijing, Guangzhou, etc). For more information, please visit: http://junshipharma.com.

Junshi Biosciences Contact Information

IR Team:
Junshi Biosciences
info@junshipharma.com
+ 86 021-6105 8800

PR Team:
Junshi Biosciences
Zhi Li
zhi_li@junshipharma.com
+ 86 021-6105 8800