Junshi Biosciences Announces Phase 3 Clinical Study of Senaparib for Advanced Ovarian Cancer Maintenance Treatment Following First-line Therapy Met Primary Endpoint

SHANGHAI, China, April 11, 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, today announced that a randomized, double-blind, placebo-controlled, multi-center phase III clinical study ("FLAMES Study", NCT04169997) investigating the poly (ADP-ribose) polymerase ("PARP") inhibitor, senaparib (product code: JS109/IMP4297), had finished its pre-specified interim analysis. Senaparib was jointly developed by Junshi Biosciences and IMPACT Therapeutics, Inc. ("IMPACT Therapeutics"), as a maintenance treatment following first-line platinum-based chemotherapy in patients with International Federation of Gynecology and Obstetrics ("FIGO") stage III/IV ovarian carcinoma, fallopian tube cancer or primary peritoneal cancer who achieved a complete response or partial response. The Independent Data Monitoring Committee (the "IDMC") concluded that the primary endpoint had met the pre-defined efficacy boundary. Junshi Biosciences and IMPACT Therapeutics will communicate with regulatory authorities regarding a new drug application for the drug in the near future.

Dr. Jianjun ZOU, President of Global Research and Development at Junshi Biosciences, commented on the positive results of the FLAMES study. "As the first phase III clinical study of a domestically developed PARP inhibitor that has achieved positive results for advanced ovarian cancer maintenance treatment following first-line therapy, the FLAMES study's interim analysis results show that senaparib can significantly extend the progression free survival (PFS) of patients with advanced ovarian cancer, regardless of the patient's breast cancer susceptibility gene (BRCA) mutation status. We will collaborate with our partner IMPACT Therapeutics to engage in communication with regulatory agencies and look forward to expanding our commercial cancer drug portfolio to provide more effective treatment options at a lower cost for patients with advanced ovarian cancer."

Ovarian cancer is one of the most commonly fatal malignant tumors affecting the female genital tract. According to GLOBOCAN 2020 data, around 310,000 new cases of ovarian cancer are diagnosed across the world annually, resulting in roughly 210,000 deaths every year. As the early symptoms of ovarian cancer are hidden and non-specific, around 80% of the patients with ovarian cancer are diagnosed at an advanced stage, with a five-year survival rate of only 40%. Although primary platinum-based chemotherapy can help alleviate ovarian cancer, most patients inevitably experience cancer relapse. Over the years, PARP inhibitor has revolutionized the treatment of ovarian cancer. In particular, PARP inhibitor maintenance treatment can extend the response time following first-line platinum-based chemotherapy and delay cancer relapse.

About the FLAMES Study

The FLAMES Study is a randomized, double-blind, placebo-controlled, multi-center phase III clinical study to evaluate the efficacy and safety of senaparib as monotherapy maintenance treatment following first-line platinum-based chemotherapy in patients with FIGO stage III/IV ovarian cancer who have achieved complete response (CR) or partial response (PR).

About Senaparib

As a novel targeted anti-tumor drug, senaparib is a PARP inhibitor. The clinical study of senaparib was supported by the national special project for innovative manufacturing of major new drugs under the 13th Five-Year Plan, and the inspection and acceptance procedures were completed smoothly. In August 2022, the fixed dose combination capsules of senaparib and temozolomide for the treatment of adult patients with small cell lung cancer was granted orphan-drug designation by the U.S. Food and Drug Administration.

In August 2020, Junshi Biosciences and IMPACT Therapeutics entered into a joint venture agreement to form a joint venture company. The joint venture company mainly engages in the research and development, and commercialization of small molecule anti-tumor drugs, including senaparib. IMPACT Therapeutics contributed the asset rights of senaparib within the joint venture territories of mainland China, Hong Kong and Macau Special Administrative Region. The Company and IMPACT Therapeutics each owns a 50% equity interest of the joint venture company.

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. Junshi Biosciences was the first Chinese pharmaceutical company that obtained marketing approval for anti-PD-1 monoclonal antibody in China. Its first-in-human anti-BTLA monoclonal antibody for the treatment of various cancers was the first in the world to be approved for clinical trials by the FDA and NMPA and has since entered Phase Ib/II trials in both China and the US. Its anti-PCSK9 monoclonal antibody was the first in China to be approved for clinical trials by the NMPA.

In the face of the pandemic, Junshi Biosciences' response was strong and immediate, joining forces with Chinese and international scientific research institutions and enterprises to develop an arsenal of drug candidates to combat COVID-19, taking the initiative to shoulder the social responsibility of Chinese pharmaceutical companies by prioritizing and accelerating COVID-19 R&D. In 2021, JS016 (etesevimab), China's first neutralizing fully human monoclonal antibody against SARS-CoV-2 administered with bamlanivimab, was granted Emergency Use Authorizations (EUA) in over 15 countries and regions worldwide. Meanwhile, VV116 (deuremidevir hydrobromide), a novel oral nucleoside analog anti-SARS-CoV-2 drug designed to hinder virus replication, has been approved for marketing in China and Uzbekistan. The JS016 and VV116 programs are a part of the company's continuous efforts towards innovation for disease control and prevention of the global pandemic.

Junshi Biosciences has about 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.

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