Junshi Biosciences Announces Acceptance of Supplemental Application for Additional Indications of Adalimumab Injection

-- Additional indications: treatment for Crohn's disease, uveitis, polyarticular juvenile idiopathic arthritis, pediatric plaque psoriasis and pediatric Crohn's disease

SHANGHAI, China, August 17, 2022 (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 today that the Company has received an Acceptance Notice issued by the National Medical Products Administration ("NMPA"). The supplemental application for additional indications of the company's adalimumab injection (project code: UBP1211, trade name: 君迈康®), including the treatment of Crohn′s disease, uveitis, polyarticular juvenile idiopathic arthritis, plaque psoriasis in children and Crohn's disease in children, has been accepted.

Tumor necrosis factor-α (TNF-α) is secreted by macrophages, mast cells and activated Th cells. It is a potent inducer of inflammatory response and a key regulator of innate immunity, playing a key role in the occurrence and development of various inflammatory conditions. The binding of TNF-α to TNF-α receptors can induce inflammatory responses, and it has been proven that rheumatoid arthritis, psoriasis, Crohn's disease, ankylosing spondylitis and many other autoimmune diseases are closely related to TNF-α. Anti-TNF-α monoclonal antibodies can bind to TNF-α receptors and reduce the immune response activated by TNF-α, thereby preventing the occurrence of inflammation.

君迈康® is jointly developed by Junshi Biosciences and Mabwell (Shanghai) Bioscience Co., Ltd. In March 2022, its indications including rheumatoid arthritis, ankylosing spondylitis and psoriasis were approved by the NMPA.

About Uveitis

Non-infectious intermediate, posterior or panuveitis (NIIPPU) is a group of immune-mediated intraocular inflammatory diseases that may cause complications such as synechia, glaucoma, cataracts, macular edema and retinopathy in patients, causing impaired vision or even blindness, and usually co-occurs with immune-mediated systemic diseases such as psoriasis and ankylosing spondylitis. According to the epidemiological research data in mainland China, its incidence rate is 152/100,000, and the incidence peaks at 24 to 44 years old.

About Crohn's Disease

It is a chronic and relapsing inflammatory gastrointestinal disease, which is categorized as inflammatory bowel disease (IBD) together with ulcerative colitis (UC). In China, the prevalence rate of Crohn's disease is 2.29/100,000, the average incidence rate is 1.21/100,000, and it is showing a rapid upward trend.

There is currently no complete cure for Crohn's disease. The goal of treatment is to induce and sustain remission, prevent complications, and improve quality of life.

About Crohn's Disease in Children

According to statistics, 25% to 30% of all IBD patients in the world are children, of which Crohn's disease accounts for the vast majority, and its incidence rate has been increasing year by year.

About Polyarticular Juvenile Idiopathic Arthritis

Juvenile idiopathic arthritis is a common rheumatic disease in childhood, with chronic joint synovitis as its main symptom. Accompanied by systemic multiple organ dysfunction, it is also an important cause of childhood disability and blindness. Polyarticular juvenile idiopathic arthritis is the most common subtype of juvenile idiopathic arthritis, accounting for about 18% to 30%.

About Plaque Psoriasis in Children

Pediatric psoriasis is an immune-mediated chronic, recurrent, inflammatory, systemic disease that occurs in children. Different populations, races, and genders are equally susceptible, and about 1/3 of patients have onset of psoriasis in childhood. The common type of psoriasis in older children is plaque psoriasis (75%), followed by guttate psoriasis (15% to 30%) and generalized pustular psoriasis (1% to 5.4%).

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. Among the many drug candidates is JS016 (etesevimab), China's first neutralizing fully human monoclonal antibody against SARS-CoV-2 and the result of the combined efforts of Junshi Biosciences, the Institute of Microbiology of the Chinese Academy of Science and Lilly. JS016 administered with bamlanivimab has been granted Emergency Use Authorizations (EUA) in over 15 countries and regions worldwide. As of December 3 2021, over 700,000 patients have been treated with bamlanivimab or bamlanivimab and etesevimab, potentially preventing more than 35,000 hospitalizations and at least 14,000 deaths. Meanwhile, VV116, a new oral nucleoside analog anti-SARS-CoV-2 drug designed to hinder virus replication, is in global Phase III clinical trials. A Phase III clinical study (NCT05341609) comparing the efficacy and safety of

VV116 versus nirmatrelvir/ritonavir (“PAXLOVID”) for patients with mild to moderate COVID-19 who are at high risk for progression to severe COVID-19, has reached its pre-specified primary endpoint and secondary efficacy endpoint. The study results show that compared to PAXLOVID, VV116 provided patients with a shorter median time to sustained clinical recovery, while achieving statistical superiority. The JS016 and VV116 programs are a part of the company’s continuous innovation for disease control and prevention of the global pandemic.

Junshi Biosciences has more than 3,100 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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