Zai Lab Announces Acceptance by China's NMPA of the BLA for Efgartigimod Alfa Injection (Subcutaneous Injection) for Patients with Generalized Myasthenia Gravis

July 10, 2023

SHANGHAI, China and CAMBRIDGE, Mass., July 10, 2023 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced that China's National Medical Products Administration (NMPA) has accepted the Biologics License Application (BLA) for efgartigimod alfa injection (subcutaneous (SC) injection, 1000mg (5.6ml)/vial) for the treatment of adult patients with generalized myasthenia gravis (gMG).

"We are pleased to have the NMPA's acceptance of the BLA for efgartigimod alfa injection for subcutaneous use. We're excited about the potential of efgartigimod to offer patients multiple ways to receive treatment through various administrations and an individualized dosing schedule," said Dr. Harald Reinhart, President and Head of Global Development, Neuroscience, Autoimmune & Infectious Diseases, Zai Lab. "As a company focused on developing innovative medicines for diseases in need of more effective treatment options, we look forward to bringing another first-in-class option for gMG patients in Greater China."

The BLA submission is supported by positive results from the global Phase 3 ADAPT-SC study, demonstrating noninferior total IgG reduction from baseline at day 29 with SC administered efgartigimod compared to intravenous (IV) administered efgartigimod in adult patients with gMG. Patients treated with efgartigimod SC achieved mean total IgG reduction of 66.4% from baseline at day 29, compared to 62.2% reduction with efgartigimod IV.

The safety profile for efgartigimod SC was also consistent with the ADAPT study. It was generally well-tolerated; the most frequent adverse event being injection site reactions (ISRs), commonly observed with biologics administered subcutaneously. All ISRs were mild to moderate and resolved over time.

In June 2023, efgartigimod alfa injection (VYVGART®) for IV use was approved by China's NMPA as an add on to standard therapy for the treatment of adult patients with gMG who are anti-acetylcholine receptor (AChR) antibody positive.

In June 2023, VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) was approved by the U.S. Food and Drug Administration (FDA) for SC use for the treatment of adult patients with gMG who are anti-AChR antibody positive.

About Efgartigimod (brand name VYVGART®)

Efgartigimod is a human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG autoantibodies. It is being investigated in several autoimmune diseases known to be mediated by disease-causing IgG antibodies, including neuromuscular disorders, blood disorders, and skin blistering diseases, in both an IV and SC formulation. SC efgartigimod is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology.

VYVGART is the first approved FcRn blocker in the United States, EU and China for the treatment of adults with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive, and in Japan for the treatment of adults with gMG who do not have sufficient response to steroids or non-steroidal immunosuppressive therapies (ISTs).

Zai Lab has an exclusive license agreement with argenx to develop and commercialize efgartigimod in mainland China, Hong Kong, Macau, and Taiwan (Greater China).

About Myasthenia Gravis in China

Myasthenia gravis (MG) is a chronic autoimmune disease, characterized by debilitating and potentially life-threatening muscle weakness. There are approximately 200,000 people in China living with the disease[1]. More than 85% of people with MG progress to gMG within 18 months; in this generalized form of the disease, skeletal muscles throughout the body may be affected, resulting in weakness and early fatigue. Difficulties with double vision, facial expression, speech, swallowing, and ambulation are frequent and difficult to manage for patients and treating physicians. In more life-threatening cases, gMG can affect the muscles responsible for breathing, which can be fatal. Acetylcholinesterase (AChE) inhibitors, steroids, immunosuppressants, and IVIg are the mainstay of treatment in China. However, there is a lack of high-level evidence-based recommendations for the treatment of MG, representing significant unmet needs.

[1] *Nationwide population-based epidemiological study of myasthenia gravis in Taiwan, 2010.*

About Zai Lab

Zai Lab (NASDAQ: ZLAB; HKEX: 9688) is an innovative, research-based, commercial-stage biopharmaceutical company based in China and the United States. We are focused on discovering, developing, and commercializing innovative products that address medical conditions with significant unmet needs in the areas of oncology, autoimmune disorders, infectious diseases, and neuroscience. Our goal is to leverage our competencies and resources to positively impact human health in China and worldwide. For additional information about Zai Lab, including our products, business activities and partnerships, research, and other events or developments, please visit www.zailaboratory.com or follow us at www.twitter.com/ZaiLab_Global.

Zai Lab Forward-Looking Statements

This press release contains forward-looking statements about future expectations, plans, and prospects for Zai Lab, including, without limitation, statements regarding the prospects of and plans for development and commercialization of efgartigimod in Greater China, the safety and efficacy of efgartigimod, and the potential treatment of patients with myasthenia gravis in Greater China. These forward-looking statements may contain words such as “aim,” “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “plan,” “possible,” “potential,” “will,” “would,” and other similar expressions. Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical fact or guarantees or assurances of future performance. Forward-looking statements are based on our expectations and assumptions as of the date of this press release and are subject to inherent uncertainties, risks, and changes in circumstances that may differ materially from those contemplated by the forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including but not limited to (1) our ability to successfully commercialize and generate revenue from our approved products, (2) our ability to obtain funding for our operations and business initiatives, (3) the results of clinical and pre-clinical development of our product candidates, (4) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of our product candidates, (5) the effects of the novel coronavirus (COVID-19) pandemic on our business and results of operations, (6) risks related to doing business in China, and (7) other factors identified in our most recent annual and quarterly reports and in other reports we have filed with the U.S. Securities and Exchange Commission (SEC). We anticipate that subsequent events and developments will cause our expectations and assumptions to change, and we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as may be required by law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

Our SEC filings can be found on our website at www.zailaboratory.com and the SEC’s website at www.sec.gov.

For more information, please contact:

Investor Relations:
Christine Chiou / Lina Zhang
+1 (917) 886-6929
christine.chiou1@zailaboratory.com / lina.zhang@zailaboratory.com

Media:
Shaun Maccoun / Xiaoyu Chen
+1 (415) 317-7255
shaun.maccoun@zailaboratory.com / xiaoyu.chen@zailaboratory.com

Zai Lab Limited

Source: Zai Lab Limited