Zai Lab and argenx Announce Approval of VYVGART® (efgartigimod alfa injection) for Generalized Myasthenia Gravis in China

June 30, 2023

First-and-only approved FcRn antagonist for gMG patients by NMPA

68% of anti-AChR antibody positive gMG patients treated with VYVGART were responders (n=44/65) on the Myasthenia Gravis Activities of Daily Living (MG-ADL) scale compared with 30% of patients treated with placebo (n=19/64) (p<0.0001) during the first treatment cycle in the Phase 3 ADAPT trial

Zai Lab to seek National Reimbursement Drug List (NRDL) inclusion for VYVGART

SHANGHAI, China and CAMBRIDGE, Mass., June 30, 2023 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) and argenx (Euronext & Nasdaq: ARGX) today announced that China's National Medical Products Administration (NMPA) has approved the Biologics License Application (BLA) for VYVGART® (efgartigimod alfa injection), a first-in-class neonatal Fc receptor (FcRn) antagonist, as an add on to standard therapy for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive. Zai Lab will now work with the National Healthcare Security Administration (NHSA) for NRDL inclusion to enable broad access for patients.

"We are pleased to have the NMPA's approval for VYVGART for intravenous use. This important milestone brings forward a novel treatment for gMG patients who face many challenges living with this complex and difficult-to-control autoimmune disease," said Dr. Samantha Du, Founder, Chairperson, and Chief Executive Officer of Zai Lab. "We appreciate the NMPA for their thorough assessment of VYVGART, recognizing its differentiated profile and the large unmet medical need in China. In addition to gMG, we are working with argenx on three registrational programs exploring other immunoglobulin G (IgG)-related autoimmune indications and are looking forward to exploring even more indications over time."

"This approval by the NMPA for VYVGART, our sixth approval globally, is the first-and-only FcRn blocker available for people living with gMG in China. This is another milestone on our path to redefine what well-controlled means for gMG patients and underscores our longstanding commitment to the global gMG community," said Tim Van Hauwermeiren, Chief Executive Officer of argenx. "We celebrate this achievement with our partner, Zai Lab, who shares our mutual passion to bring needed innovation to people with gMG in China. We look forward to continuing our partnership as we further explore efgartigimod in other indications, expanding our global footprint in one of the world's fastest growing markets to reach more people living with severe autoimmune diseases."

"There are over 200,000 people living with myasthenia gravis (MG) in China[1]. Despite the availability of current treatment options, there remains a significant unmet medical need. The approval of VYVGART in China marks an important milestone for patients and provides physicians with a novel, safe and effective therapy to help improve the quality of life for those in their care," said Dr. Chongbo Zhao, M.D., Ph.D., Deputy Director of Department of Neurology, Huashan Hospital Affiliated to Fudan University, Director of Working Group of Huashan Rare Disease Center. "In clinical studies, efgartigimod demonstrated outstanding characteristics in terms of onset of action, efficacy, and safety, helping to improve patients' muscle strength and quality of life. VYVGART, the first-and-only approved FcRn antagonist for gMG patients in China, has the potential to revolutionize the treatment landscape for gMG patients in China and we are grateful to Zai Lab for providing the support for these patients who have been devastated by this disease for so long."

The global Phase 3 ADAPT trial met its primary endpoint, demonstrating that significantly more anti-AChR antibody positive gMG patients were responders on the Myasthenia Gravis Activities of Daily Living (MG-ADL) scale following treatment with efgartigimod compared with placebo (68% vs. 30%; p<0.0001). Responders were defined as having at least a two-point reduction on the MG-ADL scale sustained for four or more consecutive weeks during the first treatment cycle[2].

There were also significantly more responders on the Quantitative Myasthenia Gravis (QMG) scale following treatment with efgartigimod compared with placebo (63% vs. 14%; p<0.0001). Responders were defined as having at least a three-point reduction on the QMG scale sustained for four or more consecutive weeks during the first treatment cycle.

VYVGART demonstrated a well-tolerated safety profile in the ADAPT clinical trial. The most commonly reported adverse reactions that occurred more frequently with VYVGART than placebo were upper respiratory tract infections (10.7% following treatment with efgartigimod vs. 4.8% of placebo) and urinary tract infections (9.5% vs. 4.8%).

About VYVGART

VYVGART is a human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG autoantibodies. It 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.

Note: China regulatory status based on the update in the NMPA system, "Approval process has been completed and the certificate is under preparation", on June 30, 2023.

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

[2] *Howard JF et al. Lancet Neurol 2021;20(7):526-536.*

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.

About argenx

argenx is a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases. Partnering with leading academic researchers through its Immunology Innovation Program (IIP), argenx aims to translate immunology breakthroughs into a world-class portfolio of novel antibody-based medicines. argenx developed and is commercializing the first approved neonatal Fc receptor (FcRn) blocker. The Company is evaluating efgartigimod in multiple serious autoimmune diseases and advancing several earlier stage experimental medicines within its therapeutic franchises. For more information, visit www.argenx.com and follow us on LinkedIn, Twitter, and Instagram.

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.

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