Zai Lab and argenx Announce Approval of Efgartigimod Alfa Injection (Subcutaneous Injection) for Generalized Myasthenia Gravis in China

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First and only NMPA-approved subcutaneous (SC) injectable providing additional flexibility and optionality for gMG patients in China

Consistent clinical benefit and safety profile of efgartigimod SC compared to IV demonstrated in Phase 3 ADAPT-SC study

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jul. 16, 2024-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) and argenx (Euronext & Nasdaq: ARGX) today announced that China's National Medical Products Administration (NMPA) approved the Biologics License Application (BLA) for efgartigimod alfa injection (subcutaneous injection) (efgartigimod SC), 1,000mg (5.6ml)/vial indicated 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.

"We are pleased to receive NMPA approval for efgartigimod SC, marking an important milestone as we bring another first-in-class option to gMG patients in China," said Rafael G. Amado, M.D., President, Head of Global Research and Development at Zai Lab. "The addition of a new treatment option for gMG patients enhances flexibility for patients, potentially further simplifying the regimen and making therapy more accessible within the community. We appreciate the NMPA for their thorough assessment and recognition of the therapy's differentiated profile and the large unmet medical need in China."

"The NMPA approval for efgartigimod SC is yet another key milestone on our journey to expand into new patient populations around the world with our transformative medicine," said Tim Van Hauwermeiren, Chief Executive Officer of argenx. "We celebrate this achievement with our partner, Zai Lab, who shares our mutual passion for bringing needed innovation to patients with gMG in China. We are impressed by the team's incredible launch execution, bringing 2,700 new patients onto VYVGART IV treatment in the first quarter of 2024, which only underscores the high unmet need that remains for gMG patients. The addition of a flexible 30-to-90 second subcutaneous injection opens the door for new patients in China, while taking into account personal preference and convenience. We look forward to continuing our partnership and expanding our footprint in one of the world's fastest growing markets to reach more people living with severe autoimmune diseases."

"There are approximately 170,000 people living with gMG in China[1]," said Prof. Xueqiang Hu, M.D., Ph.D., Chief Physician of Department of Neurology, the Third Affiliated Hospital of Sun Yat-sen University. "Compared to fixed infusion schedules, the availability of efgartigimod SC allows a more individualized and flexible treatment approach based on patient needs without sacrificing clinical benefit or safety. In the global Phase 3 ADAPT-SC study, efgartigimod SC demonstrated consistent benefit and safety compared to the intravenous product. This is a meaningful advancement for the patient community, and we are grateful to Zai Lab for supporting patients who have been devastated by this disease for so long."

The BLA approval is supported by positive results from the global Phase 3 ADAPT-SC study, a bridging study to the Phase 3 ADAPT study, which formed the basis for approval of intravenous VYVGART in adult gMG patients. In the ADAPT-SC study, the primary endpoint of noninferiority was met ($p< 0.0001$), and efgartigimod SC demonstrated mean total IgG reduction of 66.4% from baseline at day 29, compared to 62.2% with efgartigimod IV. Additional key secondary endpoints were also met, which were consistent with efficacy measures from the ADAPT study identifying the correlation between total IgG reduction and clinical benefit in gMG.

The safety profile for efgartigimod SC was also consistent with the ADAPT study. Efgartigimod SC 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.

Efgartigimod SC is also being evaluated for the potential treatment of additional autoimmune disorders. In May 2024, the NMPA accepted a supplemental Biologics License Application (sBLA) with priority review for efgartigimod SC in chronic inflammatory demyelinating polyneuropathy (CIDP). The U.S. Food and Drug Administration (FDA) approved efgartigimod SC in June 2024 for adults with CIDP.

About VYVGART® and efgartigimod SC

VYVGART (efgartigimod alfa injection) (efgartigimod IV) 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 for the treatment of adults with generalized myasthenia gravis (gMG) who are anti-AChR antibody positive.

Efgartigimod SC is a subcutaneous product including efgartigimod alfa injection, a human IgG1 antibody fragment, and recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE ® drug delivery technology to facilitate subcutaneous delivery of biologics. The product is to be administered subcutaneously as a single injection (1,000 mg fixed dose) over 30-to-90 seconds in cycles of once weekly injections for four weeks. Efgartigimod SC is approved in the United States (marketed as VYVGART® Hytrulo), EU (marketed as VYVGART® SC) and Japan (marketed as VYVDURA®).

Efgartigimod has the potential to address a multitude of severe autoimmune diseases where pathogenic IgGs are believed to be mediators of disease and is being evaluated in several autoimmune indications.

Zai Lab has an exclusive license agreement with argenx to develop and commercialize efgartigimod in mainland China, Hong Kong, Macau, and Taiwan (collectively, 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 170,000 people in China living with gMG[1], and of those patients, 85% are estimated to have confirmed AChR antibodies; 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. These drugs often achieve only partial restoration of strength.

[1] *The growing burden of generalized myasthenia gravis: a population-based retrospective cohort study in Taiwan, 2023.*

About Zai Lab

Zai Lab Limited (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 disease, 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, 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 in China, the U.S., Japan, Israel, the EU, the UK, and Canada. 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 and other autoimmune disorders 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) risks related to doing business in China, and (6) 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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