Zai Lab Partner argenx Announces U.S. Food and Drug Administration (FDA) Approval of VYVGART™ (efgartigimod alfa-fcab) in Generalized Myasthenia Gravis

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- *VYVGART is the first and only FDA-approved neonatal Fc receptor blocker*
- *68% of anti-acetylcholine receptor (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 has exclusive rights to develop and commercialize efgartigimod in Greater China and expects to file a New Drug Application (NDA) in China by mid-2022*

SHANGHAI and SAN FRANCISCO and CAMBRIDGE, Mass., Dec. 17, 2021 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), a patient-focused, innovative, commercial-stage, global biopharmaceutical company, today announced that its partner argenx SE (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases and cancer, today announced that the U.S. Food and Drug Administration (FDA) has approved VYVGART™ (efgartigimod alfa-fcab) for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. These patients represent approximately 85% of the total gMG population[1]. With this regulatory milestone, VYVGART is the first and only FDA-approved neonatal Fc receptor (FcRn) blocker.

“Today is the start of a new era for argenx and the gMG community as we honor our commitment to bring forward an innovative treatment option for people living with this debilitating disease. The approval of VYVGART represents many achievements: our first approved product; the first and only FDA-approved neonatal Fc receptor blocker; and the first approved therapy designed to reduce pathogenic IgGs, an underlying driver of gMG,” said Tim Van Hauwermeiren, Chief Executive Officer of argenx. “Importantly, we want to thank the patients, supportive caregivers, investigators and study teams who participated in the ADAPT trial, as well as our partners and dedicated employees for their hard work and collaboration – all of whom made this milestone possible.

“Our highly motivated commercial team is activated and ready to deliver VYVGART to patients. We believe the field of autoimmunity is on the precipice of an evolution, and we hope that this will be the first of many VYVGART launches, allowing us to help improve the lives of patients around the world,” continued Mr. Van Hauwermeiren.

“We congratulate our partner argenx for this first approval,” said Dr. Samantha Du, Founder, Chairperson and Chief Executive Officer of Zai Lab. “With an estimated 200,000 patients living with gMG in China, we see a great need to bring efgartigimod to Chinese patients with this autoimmune disease as expeditiously as possible. We will work closely with the China National Medical Products Administration (NMPA) to accelerate access for these patients with unmet medical needs. Efgartigimod has the potential to be the first-in-class FcRn therapy in China for gMG.”

Generalized myasthenia gravis is a rare and chronic neuromuscular disease characterized by debilitating and potentially life-threatening muscle weakness. VYVGART is a human IgG1 antibody fragment that binds to FcRn, resulting in the reduction of circulating immunoglobulin G (IgG) antibodies. The action of AChR autoantibodies at the neuromuscular junction is a key driver of gMG[2].

Proven clinical efficacy and safety profile

The approval of VYVGART is based on results from the global Phase 3 ADAPT trial, which were published in the July 2021 issue of *The Lancet Neurology*. The ADAPT trial met its primary endpoint, demonstrating that significantly more anti-AChR antibody positive gMG patients were responders on the MG-ADL scale following treatment with VYVGART 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.

There were additionally significantly more responders on the Quantitative Myasthenia Gravis (QMG) scale following treatment with VYVGART 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 had a demonstrated safety profile in the ADAPT clinical trial. The most common adverse events in ADAPT were respiratory tract infection (33% vs 29% placebo), headache (32% vs 29% placebo), and urinary tract infection (10% vs. 5% placebo).

Marketing Authorization Applications for efgartigimod for the treatment of gMG are currently under review with Japan’s Pharmaceuticals and Medical Devices Agency (PMDA) and the European Medicines Agency (EMA), with anticipated decisions from each agency in the first quarter and second half of 2022, respectively.

See Important Safety Information and full Prescribing Information below for additional information.

IMPORTANT SAFETY INFORMATION

What is VYVGART™(efgartigimod alfa-fcab)?

VYVGART is a prescription medicine used to treat a condition called generalized myasthenia gravis, which causes muscles to tire and weaken easily throughout the body, in adults who are positive for antibodies directed toward a protein called acetylcholine receptor (anti-AChR antibody positive).

What is the most important information I should know about VYVGART?

VYVGART may cause serious side effects, including:

- **Infection.** VYVGART may increase the risk of infection. In a clinical study, the most common infections were urinary tract and respiratory tract infections. More patients on VYVGART vs placebo had below normal levels for white blood cell counts, lymphocyte counts, and neutrophil counts. The majority of infections and blood side effects were mild to moderate in severity. Your health care provider should check you for infections before starting treatment, during treatment, and after treatment with VYVGART. Tell your health care provider if you have any history of infections. Tell your health care provider right away if you have signs or symptoms of an infection during treatment with VYVGART such as fever, chills, frequent and/or painful urination, cough, pain and blockage of nasal passages/sinus, wheezing, shortness of breath, fatigue, sore throat, excess phlegm, nasal discharge, back pain, and/or chest pain.
- **Undesirable immune reactions (hypersensitivity reactions).** VYVGART can cause the immune system to have undesirable reactions such as rashes, swelling under the skin, and shortness of breath. In clinical studies, the reactions were mild or moderate and occurred within 1 hour to 3 weeks of administration, and the reactions did not lead to VYVGART discontinuation. Your health care provider should monitor you during and after treatment and discontinue VYVGART if needed. Tell your health care provider immediately about any undesirable reactions.

Before taking VYVGART, tell your health care provider about all of your medical conditions, including if you:

- Have a history of infection or you think you have an infection
- Have received or are scheduled to receive a vaccine (immunization). Discuss with your health care provider whether you need to receive age-appropriate immunizations before initiation of a new treatment cycle with VYVGART. The use of vaccines during VYVGART treatment has not been studied, and the safety with live or live-attenuated vaccines is unknown. Administration of live or live-attenuated vaccines is not recommended during treatment with VYVGART.
- Are pregnant or plan to become pregnant and are breastfeeding or plan to breastfeed.

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the common side effects of VYVGART?

The most common side effects of VYVGART are respiratory tract infection, headache, and urinary tract infection.

These are not all the possible side effects of VYVGART. Call your doctor for medical advice about side effects. You may report side effects to the US Food and Drug Administration at 1-800-FDA-1088.

Please see the full Prescribing Information for VYVGART and talk to your doctor.

About Phase 3 ADAPT Trial

The Phase 3 ADAPT trial was a 26-week randomized, double-blind, placebo-controlled, multi-center, global trial evaluating the safety and efficacy of VYVGART in adult patients with gMG. A total of 167 adult patients with gMG in North America, Europe and Japan enrolled in the trial. Patients were randomized in a 1:1 ratio to receive VYVGART or placebo, in addition to stable doses of their current gMG treatment. ADAPT was designed to enable an individualized treatment approach with an initial treatment cycle followed by subsequent treatment cycles based on clinical evaluation. The primary endpoint was the comparison of percentage of MG-ADL responders in the first treatment cycle between VYVGART and placebo treatment groups in the anti-AChR antibody positive population.

About VYVGART

VYVGART (efgartigimod alfa-fcab) is a human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG. It is the first and only approved FcRn blocker. VYVGART is approved in the United States for the treatment of adults with generalized myasthenia gravis (gMG) who are anti-AChR antibody positive.

About Generalized Myasthenia Gravis

Generalized myasthenia gravis (gMG) is a rare and chronic autoimmune disease where IgG autoantibodies disrupt communication between nerves and muscles, causing debilitating and potentially life-threatening muscle weakness. Approximately 85% of people with MG progress to gMG within 24 months[1], where muscles throughout the body may be affected. Patients with confirmed AChR antibodies account for approximately 85% of the total gMG population[1].

About Zai Lab

Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) is a patient-focused, innovative, commercial-stage, global biopharmaceutical company focused on

developing and commercializing therapies that address medical conditions with unmet needs in oncology, autoimmune disorders, infectious diseases, and neuroscience. To that end, our experienced team has secured partnerships with leading global biopharmaceutical companies in order to generate a broad pipeline of innovative marketed products and product candidates. We have also built an in-house team with strong product discovery and translational research capabilities and are establishing a pipeline of proprietary product candidates with global rights. Our vision is to become a leading global biopharmaceutical company, discovering, developing, manufacturing, and commercializing our portfolio in order to impact human health worldwide.

For additional information about the company, please visit www.zailaboratory.com or follow us at www.twitter.com/ZaiLab_Global.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects for Zai Lab, including, without limitation, statements regarding the prospects of and plans for commercializing efgartigimod in the Greater China region. 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, nor are they 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 finance our operations and business initiatives and obtain funding for such activities, (3) our 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 general economic, regulatory, and political conditions, and (6) the risk factors identified in our most recent annual or quarterly report and in other reports we have filed with the U.S. Securities and Exchange Commission. 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.

For more investor-related information about Zai Lab, please go to www.SEC.gov or visit www.zailaboratory.com.

References

[1] Behin et al. New Pathways and Therapeutics Targets in Autoimmune Myasthenia Gravis. J Neuromusc Dis 5. 2018. 265-277

[2] Howard JF Jr, Utsugisawa K, Benatar M, et al. Safety and efficacy of efficacy of eculizumab in anti-acetylcholine receptor antibody-positive refractory generalised myasthenia gravis (REGAIN): a phase 3, randomised, double-blind, placebo-controlled, multicenter study. *Lancet Neurol*. 2017; 16: 976-86

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