Zai Lab and argenx Announce Positive Topline Results from Phase 3 ALKIVIA Trial of Efgartigimod in Autoimmune Myositis

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- *Study met primary endpoint of mean Total Improvement Score (TIS) at Week 52 in the combined study population of IMNM and DM patients (p=0.0011)*
- *Patient improvements observed early and sustained throughout study; consistent treatment effect across IMNM and DM*
- *First Phase 3 study to show statistically significant and clinically meaningful improvements in disease activity in IMNM, a subtype with no approved therapy*

SHANGHAI & CAMBRIDGE, Mass. & AMSTERDAM--(BUSINESS WIRE)--Aug. 17, 2026-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) and argenx (Euronext & NASDAQ: ARGX), today announced positive topline results from the ALKIVIA Phase 3 study evaluating VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) in adults with autoimmune myositis.

Study met its primary endpoint (p=0.0011)

- In the combined immune-mediated necrotizing myopathy (IMNM) and dermatomyositis (DM) population, patients treated with efgartigimod demonstrated statistically significant and clinically meaningful 15.4 point greater improvement in mean Total Improvement Score (TIS) at Week 52 versus placebo (47.95 vs 32.56).

Rapid and sustained treatment benefit

- In the combined population, patients treated with efgartigimod consistently showed improvements over placebo starting at Week 4 that were statistically significant and sustained through the full year of treatment, even with steroid tapering.

Magnitude of clinical improvement consistent across both IMNM and DM

- In prespecified subtype analyses, the primary endpoint of Mean TIS at 52 weeks was also met in IMNM patients treated with efgartigimod (p=0.0048), with a 14.8 point greater improvement over placebo (45.05 vs 30.24). In DM, a similar clinically meaningful improvement of 14.5 points (p=0.1093) was observed (51.51 vs 36.96), though statistical significance was not reached in this smaller cohort.

Clinical impact observed in both muscle and skin measures

- In both IMNM and DM, all six core set measures of TIS contributed to the treatment effect, each favoring efgartigimod over placebo, spanning muscle strength, everyday physical function, and disease activity beyond the muscle. In DM, improvement in skin disease activity was also observed.

Efgartigimod was well-tolerated by patients in the ALKIVIA study. The observed safety profile was consistent with prior studies and the known safety profile of efgartigimod.

“The Phase 3 ALKIVIA results demonstrate a clinically meaningful and statistically significant treatment benefit in the overall study population, including a significant improvement in patients with IMNM, a subtype with no approved therapies,” said Rafael G. Amado, M.D., President, Head of Global Research and Development at Zai Lab. “For patients in China living with autoimmune myositis, these results offer hope for a new targeted treatment option that could meaningfully improve muscle strength, physical function and other manifestations of this debilitating disease. Zai Lab is proud to have participated in this global trial and looks forward to working with argenx to bring this therapy to patients in China as quickly as possible.”

"For decades, people living with autoimmune myositis have relied on corticosteroids and broad immunosuppression, and those with IMNM have had no approved option at all. These are the first Phase 3 results to show that precision targeting of FcRn with efgartigimod can deliver meaningful benefit in this disease," said Luc Truyen, M.D., Ph.D., Chief Medical Officer at argenx. “The patient response to efgartigimod was durable and multidimensional: separation from placebo emerged early and held through a full year of treatment, with a treatment effect of comparable magnitude in IMNM and DM. This confirms that pathogenic IgG autoantibodies are key drivers of autoimmune myositis. We are grateful to the patients, caregivers, and investigators who made this pioneering study possible."

“For people living with myositis, the goal is straightforward: regain strength and function, and get off long-term steroids. Until now we have had limited targeted therapies to offer patients,” said Rohit Aggarwal, M.D., M.S., Professor of Medicine and Co-Director of the Myositis Center at the University of Pittsburgh, and an ALKIVIA investigator. “IMNM is the most refractory form of this disease and many of these patients carry irreversible muscle damage, which makes meaningful improvement genuinely difficult to achieve. That is what makes these results so compelling and groundbreaking. In DM, the magnitude of improvement was comparable – and for a community where treatment options remain limited and the burden of chronic steroids

is just as heavy, that matters. Together these results tell us that reducing pathogenic autoantibodies is clinically meaningful and a major step forward for patients who are in need of a targeted treatment."

Detailed results from the ALKIVIA study will be presented at an upcoming medical meeting.

Efgartigimod continues to be evaluated as a potential treatment in other autoimmune rheumatologic diseases, including Sjögren's disease and systemic sclerosis.

About the ALKIVIA Study

The ALKIVIA study was a global, randomized, double-blind, placebo-controlled, multicenter, operationally seamless Phase 2/3 study of efgartigimod SC for the treatment of autoimmune myositis across IMNM, DM and PM. The ALKIVIA study enrolled 264 patients who had active disease and were on background treatment. Participants were randomized (1:1) to receive weekly injections of efgartigimod PH20 SC or matched placebo PH20 SC. The study was conducted in two phases, with an analysis of the Phase 2 portion of the clinical trial after the first 89 patients completed the study, followed by Phase 3. The Phase 3 study enrolled 175 patients and included a protocol-mandated corticosteroid taper throughout the study. The primary endpoint of Phase 3 was the mean Total Improvement Score (TIS) at the end of the treatment period of 52 weeks of all treated patients compared to placebo. Prespecified analyses evaluated the combined IMNM and DM population and each subtype separately.

argenx has an exclusive license agreement with Zai Lab for the development and commercialization of VYVGART and VYVGART Hytrulo in Greater China. Through this agreement, Zai Lab recruited Chinese patients into the ALKIVIA trial.

About Autoimmune Myositis

Autoimmune myositis is a heterogenous disease spectrum with autoimmune-mediated pathophysiology, characterized by chronic inflammation and progressive muscle weakness, and in some subtypes by skin involvement and other extramuscular manifestations. Proximal muscle weakness is a hallmark clinical feature across subtypes.

Approximately 100,000 people in the United States live with autoimmune myositis, including approximately 20,000 with IMNM and approximately 40,000 with DM. Up to 80 percent of patients report long-term disability despite treatment. There are currently no targeted treatments available, and care relies primarily on corticosteroids and broad immunosuppressants, which are associated with significant cumulative toxicity, including metabolic, cardiovascular, musculoskeletal and infectious complications.

Advances in the understanding of autoimmune myositis biology have highlighted the central role of antibody-mediated immunity, with pathogenic IgG autoantibodies contributing to muscle fiber damage and extramuscular manifestations across subtypes. FcRn maintains circulating IgG levels by recycling IgG antibodies, including pathogenic autoantibodies. Efgartigimod is designed to selectively block FcRn, reducing pathogenic IgG autoantibodies while preserving other aspects of immune function.

About VYVGART

VYVGART® (efgartigimod alfa fcab) is a first-in-class human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG autoantibodies. VYVGART Hytrulo® is a subcutaneous combination of efgartigimod alfa (VYVGART) and recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology to facilitate subcutaneous injection delivery of biologics. VYVGART is approved for generalized myasthenia gravis (gMG) and immune thrombocytopenia (Japan only). VYVGART Hytrulo is approved for gMG and chronic inflammatory demyelinating polyneuropathy (CIDP). VYVGART Hytrulo may be marketed under different proprietary names in other regions.

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, immunology, neuroscience, and infectious disease. Our goal is to leverage our competencies and resources to positively impact human health.

For additional information about Zai Lab, please visit www.zailaboratory.com or follow us at https://x.com/ZaiLab_Global.

About argenx

argenx is a global immunology innovation 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 and is evaluating its broad potential in multiple serious autoimmune diseases while advancing several earlier stage experimental medicines within its therapeutic franchises. For more information, visit www.argenx.com and follow us on LinkedIn, Instagram, Facebook, and YouTube.

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 autoimmune myositis 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.

This press release contains inside information within the meaning of Article 7(1) of the EU Market Abuse Regulation (Regulation 596/2014).

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