Zai Lab and argenx Report Positive Topline Data from ADHERE Study of VYVGART Hytrulo in Patients with Chronic Inflammatory Demyelinating Polyneuropathy

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- Study met primary endpoint (p=0.000039); VYVGART® Hytrulo demonstrated 61% reduction (HR: 0.39 95% CI: 0.25; 0.61) in risk of relapse versus placebo
- IgG autoantibodies shown to play significant role in underlying CIDP disease biology
- Favorable safety and tolerability profile consistent with previous clinical trials and confirmed safety profile of VYVGART®
- Zai Lab enrolled a significant number of patients in the Greater China portion of the global ADHERE study

SHANGHAI, China and CAMBRIDGE, Mass., July 17, 2023 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) and argenx SE (Euronext & Nasdaq: ARGX) today announced positive topline results from the ADHERE study evaluating VYVGART Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) in adults with chronic inflammatory demyelinating polyneuropathy (CIDP). The study met its primary endpoint (p=0.000039), demonstrating a significantly lower risk of relapse with VYVGART Hytrulo compared to placebo. Detailed data from ADHERE will be presented at an upcoming medical meeting.

ADHERE Highlights

- Primary endpoint met (p=0.000039); VYVGART Hytrulo demonstrated 61% reduction (HR: 0.39 95% CI: 0.25; 0.61) in the risk of relapse versus placebo
- 67% of patients in open-label Stage A demonstrated evidence of clinical improvement (ECI), indicating that IgG autoantibodies play a significant role in the underlying biology of CIDP
- Safety and tolerability profile consistent with confirmed safety profile of VYVGART
- 91% (226/249) of eligible patients continued to the ADHERE-Plus open-label extension study

“CIDP is a rare chronic immune-mediated peripheral neuropathy characterized by weakness and sensory dysfunction in the limbs, significantly impacting the daily life and work of patients,” 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. “Currently, intravenous immunoglobulin (IVIg), plasma exchange (PLEX), and glucocorticoids are the main treatments used during the induction and maintenance phases. However, the accessibility and convenience of IVIg and PLEX are limited, and glucocorticoids have significant side effects, leaving urgent needs for treatment options that are more effective and safe. We are excited about the therapeutic potential of VYVGART Hytrulo, a promising treatment that may become a therapeutic alternative for CIDP in China.”

“The positive ADHERE trial data provides strong clinical evidence that VYVGART Hytrulo meaningfully improves and stabilizes disease symptoms in CIDP patients with a favorable safety profile and a simple route of administration,” said Dr. Harald Reinhart, President and Head of Global Development, Neuroscience, Autoimmune & Infectious Diseases, Zai Lab. “We are proud to have contributed to the ADHERE study and are looking forward to working with our partner to bringing this therapy to CIDP patients in China.”

Detailed ADHERE Results

ADHERE is the largest clinical trial of CIDP patients to date, enrolling adults who were treatment naïve (not on active treatment within the past six months) or currently on immunoglobulin therapy or corticosteroids. The trial consisted of a run-in period where current treatment was stopped followed by an open-label Stage A, after which responders to VYVGART Hytrulo advanced to a randomized, placebo-controlled Stage B.

322 patients enrolled in Stage A and received treatment with VYVGART Hytrulo.

- 67% (214/322) demonstrated evidence of clinical improvement (ECI) after a run-in withdrawal period based on the Inflammatory Neuropathy Cause and Treatment (INCAT) Disability Score, the Inflammatory Rasch-built Overall Disability Scale (I-RODS) or grip strength
- 70% (214/304) demonstrated ECI excluding patients ongoing in Stage A at the time of the 88th event who did not have the

full opportunity to achieve a response
- 78% (214/275) demonstrated ECI in a sensitivity analysis of patients who received at least four injections to reach the full IgG-lowering effect of VYVGART Hytrulo
- Response rates similar across all prior CIDP medication subgroups with consistent efficacy on INCAT, I-RODS and grip strength

221 responders from Stage A entered Stage B, where the primary endpoint was the relative risk of relapse based on time to relapse on the INCAT Disability Score.

- VYVGART Hytrulo significantly reduced the risk of CIDP relapse compared to placebo
  - Primary endpoint was met (p=0.000039); VYVGART Hytrulo demonstrated a 61% reduction (HR: 0.39 95% CI: 0.25; 0.61) in the risk of relapse compared to placebo based on time to the first adjusted INCAT deterioration of ≥1 point
  - VYVGART Hytrulo patients had a lower relapse rate compared to placebo at Week 24 (26% versus 54%) and Week 48 (34% versus 60%)
  - VYVGART Hytrulo patients experienced longer time to relapse compared to those on placebo with a rapid separation of the Kaplan–Meier curves beginning at Week 4 and sustained through Week 48
  - VYVGART Hytrulo patients demonstrated a clinically meaningful mean improvement of 7.7 points on I-RODS and 12.3kPa on grip strength in Stage A. This clinically meaningful benefit was maintained in Stage B by treated patients and lost in placebo patients
  - Clinical benefit observed across all efficacy scales and patient subgroups, regardless of prior therapy

VYVGART Hytrulo was well-tolerated with a safety profile that is consistent with prior clinical trials and the known profile of VYVGART. The most frequent treatment-related adverse event was injection site reactions (ISRs), which occurred in a lower percentage of patients than previous VYVGART Hytrulo trials (20% in Stage A; 10% in Stage B). All ISRs were mild to moderate and resolved over time.

Zai Lab has an exclusive license agreement with argenx for the development and commercialization of VYVGART and VYVGART Hytrulo in Greater China. Through this agreement, Zai Lab dosed the first patient in the Greater China portion of the global registrational ADHERE trial in November 2021, and contributed a significant number of patients into this trial.

About ADHERE Trial Design

The ADHERE trial was a multicenter, randomized, double-blind, placebo-controlled trial evaluating VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP). ADHERE enrolled 322 adult patients with CIDP who were treatment naïve (not on active treatment within the past six months or newly diagnosed) or being treated with immunoglobulin therapy or corticosteroids. The trial consisted of an open-label Stage A followed by a randomized, placebo-controlled Stage B. In order to be eligible for the trial, the diagnosis of CIDP was confirmed by an independent panel of experts. Patients entered a run-in stage, where any ongoing CIDP treatment was stopped and in order to be eligible for Stage A had to demonstrate active disease, with clinically meaningful worsening on at least one CIDP clinical assessment tool, including INCAT, I-RODS, or mean grip strength. Treatment naïve patients were able to skip the run-in period with proof of recent worsening. To advance to Stage B, patients needed to demonstrate evidence of clinical improvement (ECI) with VYVGART Hytrulo. ECI was achieved through improvement of the INCAT score, or improvement on I-RODS or mean grip strength if those scales had demonstrated worsening during the run-in period. In Stage B, patients were randomized to either VYVGART Hytrulo or placebo for up to 48 weeks. The primary endpoint was measured once 88 total relapses or events were achieved in Stage B and was based on the hazard ratio for the time to first adjusted INCAT deterioration (i.e. relapse). After Stage B, all patients had the option to roll-over to an open-label extension study to receive VYVGART Hytrulo.

About Chronic Inflammatory Demyelinating Polyneuropathy

Chronic inflammatory demyelinating polyneuropathy (CIDP) is a rare and serious autoimmune disease of the peripheral nervous system. Although confirmation of disease pathophysiology is still emerging, there is increasing evidence that IgG antibodies play a key role in the damage to the peripheral nerves. People with CIDP experience fatigue, muscle weakness and a loss of feeling in their arms and legs that can get worse over time or may come and go. These symptoms can significantly impair a person's ability to function in their daily lives. Without treatment, one-third of people living with CIDP will need a wheelchair.

About CIDP in China

The prevalence of CIDP in China is estimated at 50,000 patients.[1] Current treatment options are primarily corticosteroids and intravenous immunoglobulin (IVIg), with plasma exchange (PLEX) generally reserved for refractory patients. There is limited access to PLEX or IVIg in many parts of the world, including China. As most patients require treatment for an extended period of time there remains a significant unmet need for alternate treatment options that are effective, well-tolerated, and convenient for patients with CIDP in China.

[1] *Chronic inflammatory demyelinating polyneuropathy and diabetes, 2020.*

About VYVGART® Hytrulo

VYVGART Hytrulo is a subcutaneous combination of efgartigimod alfa, a human IgG1 antibody fragment marketed for intravenous use as VYVGART®, and recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE ® drug delivery technology to facilitate subcutaneous

injection delivery of biologics. In binding to the neonatal Fc receptor (FcRn), VYVGART Hytrulo results in the reduction of circulating IgG. It is the first-and-only approved FcRn blocker administered by subcutaneous injection.

VYVGART Hytrulo is the proprietary name in the U.S. for subcutaneous efgartigimod alfa and recombinant human hyaluronidase PH20. It may be marketed under different proprietary names following approval in other regions.

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 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 chronic inflammatory demyelinating polyneuropathy 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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