Zai Lab Partner argenx Announces Positive Phase 3 Data from ADVANCE Trial of VYVGART® (efgartigimod alfa-fcab) in Adults with Primary Immune Thrombocytopenia

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- Study met primary endpoint, demonstrating a higher proportion of sustained platelet response with VYVGART treatment compared to placebo (p=0.0316); responders observed across patient types regardless of prior therapy or disease severity

- Statistically significant separation from placebo in key platelet-derived secondary endpoints

- Safety and tolerability profile of VYVGART is consistent with previous clinical trials; ADVANCE is first registrational trial with chronic dosing out to 24 weeks

- Topline data expected in first quarter 2023 from ADVANCE-SC, the second pivotal trial required for registration in primary immune thrombocytopenia (ITP)

SHANGHAI, China and SAN FRANCISCO and CAMBRIDGE, Mass., May 05, 2022 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced that the company's partner argenx (Euronext & Nasdaq: ARGX) reported positive data from the Phase 3 ADVANCE trial of VYVGART® (efgartigimod alfa-fcab).

In adults with primary ITP, ADVANCE met its primary endpoint demonstrating that a higher proportion of chronic ITP patients receiving VYVGART achieved a sustained platelet count response compared to placebo. ADVANCE is the first Phase 3 clinical trial of a neonatal Fc receptor (FcRn) blocker in ITP.

The ADVANCE trial enrolled 131 adult patients with chronic and persistent ITP. Patients were heavily pretreated and 67% of patients had received three or more prior ITP therapies, including 59% who had prior thrombopoietin receptor agonist (TPO-RAs) experience, 34% with prior rituximab experience and 37% with a history of splenectomy. Patients were insufficiently controlled at baseline with mean platelet counts of $17x10^9$/L across all patients. Of patients who completed the full ADVANCE study, 94% (63/67) of VYVGART-treated patients and 97% (38/39) of placebo patients continued to the ADVANCE+ open-label extension study.

Highlights of Phase 3 ADVANCE Data

Primary endpoint met

ADVANCE met its primary endpoint demonstrating a significantly higher proportion of patients with chronic ITP receiving VYVGART (17/78; 21.8%) compared to placebo (2/40; 5%) achieved a sustained platelet response (p=0.0316), defined as having platelet counts greater than or equal to $50x10^9$/L on at least four of the last six scheduled visits between weeks 19 and 24 of treatment.

Primary endpoint responders were observed across patient types regardless of age, disease severity, time since diagnosis, prior ITP treatment or background medication.

Key platelet-derived secondary endpoints demonstrated statistical significance

Key platelet-derived secondary endpoints showed VYVGART-treated patients had a statistically significant benefit compared to placebo on (1) cumulative number of weeks where platelet counts were at least $50x10^9$/L in the chronic ITP population (p=0.0009) and (2) sustained platelet response in the overall population, including both chronic and persistent ITP patients (p=0.0108). Numerically fewer WHO-classified bleeding events occurred in treated patients throughout the trial but the difference from placebo was not statistically significant. A higher proportion of treated patients in the overall population achieved a durable, sustained platelet response compared to placebo, defined as a sustained platelet response on at least six of the last eight scheduled visits between weeks 17 and 24 of treatment (p=0.0265), but was not considered statistically significant based on hierarchical testing.

Additional secondary endpoints provided clinically meaningful data on platelet count responses throughout 24-week trial

Additional secondary endpoint data from the ADVANCE trial are consistent with primary and secondary platelet-derived endpoints and provide additional context on metrics that often drive treatment decisions.

- **International Working Group (IWG) responder status**: 51.2% of VYVGART-treated patients were classified as IWG responders and 27.9% as complete responders compared to 20% of placebo patients as IWG responders and 4.4% as complete responders. IWG responders are defined as having a platelet count of at least $30x10^9$/L, a two-fold increase in platelet count from baseline, and the absence of bleeding for two separate, consecutive weekly visits. Complete

responders are patients with platelet counts of $100x10^9$/L and the absence of bleeding for two separate, consecutive weekly visits.

- **Mean platelet count change from baseline**: VYVGART-treated patients demonstrated a rapid onset of platelet count improvement with statistically significant separation from placebo observed at week one and maintained through 20 out of 24 weeks of the trial.
- **Switch to biweekly dosing**: Ten VYVGART-treated patients switched to a biweekly (every two weeks) dosing schedule after achieving platelet counts of $100x10^9$/L for three out of four consecutive visits, compared to one placebo patient. Nine of the ten treated patients achieved a sustained platelet response.

Consistent safety and tolerability profile

ADVANCE is the second registrational trial of VYVGART and the first to evaluate chronic weekly dosing. VYVGART was well-tolerated in this 24-week study and the observed safety and tolerability profile was consistent with previous clinical trials.

The Phase 3 ADVANCE trial is the first of two registrational trials being conducted as part of the ongoing ITP development program. ADVANCE-SC is evaluating subcutaneous efgartigimod for the treatment of primary ITP.

In November 2021, Zai Lab announced that the first patient with primary ITP was treated with efgartigimod in Greater China (mainland China, Hong Kong, Macau, and Taiwan) as part of the global registrational ADVANCE-SC Phase 3 study.

Topline data from the ADVANCE-SC study are expected in the first quarter of 2023.

Phase 3 ADVANCE Trial Design

The Phase 3 ADVANCE trial was a randomized, double-blind, placebo-controlled, multicenter, global trial evaluating the efficacy and safety of VYVGART in adult patients with chronic or persistent primary ITP. A total of 131 adult patients with primary ITP in North America, Europe and Japan enrolled in the trial and received VYVGART or placebo for a total of 24 weeks as part of the primary trial. Enrolled patients had a confirmed ITP diagnosis and a mean entry platelet count of less than $30x10^9$/L. Patients were on a stable dose of at least one ITP treatment prior to randomization and had received at least one prior therapy. Concomitant medications permitted included corticosteroids, nonsteroidal immunosuppressive drugs, fostamatinib or TPO-RAs. If patients were on 'watch and wait' at baseline, they had to have received at least 2 prior treatments for ITP.

Patients were randomized in a 2:1 ratio to receive VYVGART or placebo for a total of 24 weeks as part of the primary trial. Randomized patients received weekly infusions from weeks 1-4 and were eligible to adjust frequency to bi-weekly depending on platelet count. Administration frequency was fixed from study visits 16-24. The primary endpoint was measured by the proportion of patients with chronic ITP with a sustained platelet count response defined as achieving platelet counts of greater than or equal to $50x10^9$/L for at least four of the last six scheduled visits between weeks 19 and 24. Patients who received rescue therapy at week 12 or later, or for whom dose and/or frequency of concurrent ITP therapies increased at week 12 or later, were considered non-responders. Key secondary endpoints included extent of disease control over 24-week treatment period, proportion of overall population with sustained platelet count response, incidence and severity of WHO-classified bleeding events and an extended primary endpoint analysis between weeks 17 and 24.

About Immune Thrombocytopenia (ITP)

Immune thrombocytopenia (ITP) is an autoimmune disorder where immunoglobulin G (IgG) autoantibodies destroy platelets and reduce platelet production, which can lead to an increased risk of excessive bleeding and bruising. In severe cases, frequent bleeding events can cause anemia or even brain hemorrhage in rare cases. ITP is also associated with debilitating fatigue and significant impacts on mental health, including anxiety, fear and depression. Many ITP patients are inadequately controlled on current therapies so there remains a significant unmet need for additional treatment options.

About ITP in China

The prevalence of ITP in Greater China is estimated at 120,000 patients. Current first-line treatments are corticosteroids and intravenous immunoglobulin (IVIg). However, there are concerns about side effects of corticosteroids, and there is limited access to IVIg therapy. Second-line treatment options are primarily thrombopoietic agents, rituximab, and splenectomy. Despite availability of these treatments with differing mechanisms of action, many patients develop resistance to treatment and are prone to relapse. There remains a significant need for new treatment options.

About VYVGART® (efgartigimod alfa-fcab)

VYVGART is a human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating immunoglobulin G (IgG) autoantibodies. 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-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). VYVGART is being studied in adults with primary immune thrombocytopenia (ITP) and other IgG autoantibody-mediated diseases.

Zai Lab has an exclusive license agreement with argenx to develop and commercialize efgartigimod in Greater China.

About Zai Lab

Zai Lab (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 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 to impact human health worldwide.

For additional information about Zai Lab, including information on our products, business activities and partnerships, research, or other events or developments that may be of interest to investors, 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, including, without limitation, statements regarding the possible benefits, safety and efficacy of efgartigimod, the identification and treatment of primary immune thrombocytopenia, and risks and uncertainties associated with drug development and commercialization. These statements may be identified by 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 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 our 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, (6) risks related to doing business in China and (7) the other 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 information about our SEC filings, please go to www.SEC.gov.

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