Zai Lab Announces First Patient Dosed in Greater China in Global Registrational Clinical Trial of Efgartigimod in Primary Immune Thrombocytopenia

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SHANGHAI and SAN FRANCISCO and CAMBRIDGE, Mass., Nov. 11, 2021 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), is a patient-focused, innovative, commercial-stage, global biopharmaceutical company. The company announced today that the first patient with primary immune thrombocytopenia (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. The ADVANCE-SC study is a randomized, double-blind, placebo-controlled, multi-center Phase 3 trial evaluating the efficacy and safety of subcutaneous (SC) efgartigimod in approximately 156 adult patients with primary ITP.

In a prior Phase 2 study[1], patients treated with efgartigimod exhibited clinically meaningful improvement in platelet counts across doses and types of ITP patients (newly diagnosed, persistent and chronic), and this benefit strongly correlated with reduction in IgG levels. This data highlights the potency of efgartigimod in this difficult-to-treat disease. Efgartigimod has the potential to treat ITP in a novel way, targeting the disease at its source by eliminating autoantibodies and restoring platelet counts. Also, efgartigimod appears to be well tolerated, potentially because of its unique structure and ability to bind to the FcRn receptor.

ITP is a rare and often chronic bleeding disorder in which reduced numbers of platelets can lead to an increased risk of bleeding and bruising, which impairs quality of life. In ITP, the immune system produces IgG autoantibodies that destroy platelets and affect platelet production. While ITP can be asymptomatic, minor bleeding episodes are not uncommon. Some ITP patients experience more severe bleeding episodes, including intracerebral hemorrhage.

About Primary ITP in China

The prevalence of primary 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 Efgartigimod

Efgartigimod is an investigational antibody fragment designed to reduce pathogenic immunoglobulin G (IgG) antibodies by binding to the neonatal Fc receptor and blocking the IgG recycling process. Efgartigimod is being investigated in several autoimmune diseases known to be mediated by disease-causing IgG antibodies, including neuromuscular disorders, blood disorders, and skin blistering diseases. Such diseases include myasthenia gravis (MG), pemphigus vulgaris and foliaceus (PV and PF), immune thrombocytopenia (ITP), chronic inflammatory demyelinating polyneuropathy (CIDP), bullous pemphigoid, and idiopathic inflammatory myopathy (myositis).

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 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, 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 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) 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 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 information, please contact:

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[1] A Newland et al. Phase 2 study of efgartigimod, a novel FcRn antagonist, in adult patients with primary immune thrombocytopenia. Am J Hematol. 2020;95:178–187

Source: Zai Lab Limited