Zai Lab Announces First Patient Dosed in Greater China in Global Registrational Clinical Trial of Efgartigimod in CIDP

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SHANGHAI and SAN FRANCISCO and CAMBRIDGE, Mass., Nov. 16, 2021 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), a patient-focused, innovative, commercial-stage, global biopharmaceutical company, today announced that the first patient has been dosed in the Greater China portion of the global registrational ADHERE study of efgartigimod in patients with chronic inflammatory demyelinating polyneuropathy (CIDP).

The ADHERE trial is a registrational, prospective, multi-center study to investigate the safety and efficacy of weekly subcutaneous (SC) efgartigimod in adult patients with CIDP. The trial consists of an open-label Stage A followed by a randomized, placebo-controlled Stage B. Diagnosis of CIDP will be confirmed by an independent panel of experts prior to enrollment into Stage A. In Stage B, patients are randomized to either SC efgartigimod or placebo for up to 48 weeks. The primary endpoint is event-driven and based on the adjusted Inflammatory Neuropathy Cause and Treatment (INCAT) overall disability score.

“CIDP is a chronic and progressive disease characterized by progressive weakness and impaired sensory function in the legs and arms for which limited effective and well-tolerated treatment options exist,” said Harald Reinhart, M.D., Chief Medical Officer, Autoimmune and Infectious Diseases at Zai Lab. “Due to the side effects of corticosteroids and limited access to intravenous immunoglobulin (IVIg) therapy in China, we are excited about the therapeutic potential of efgartigimod in CIDP and look forward to advancing the China portion of this registrational study.”

Chronic inflammatory demyelinating polyneuropathy (CIDP) is a 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 can 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. Current treatment options are primarily corticosteroids and intravenous immunoglobulin (IVIg). Plasmapheresis (plasma exchange) is an option when first-line therapy fails. However, there is limited access to plasmapheresis or IVIg in many parts of the world, including China. As most patients require treatment for a rather prolonged time, there remains a significant unmet need for alternate treatment options that are effective, well-tolerated, and convenient for patients with CIDP in China.

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 chronic inflammatory demyelinating polyneuropathy, 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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