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

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SHANGHAI and SAN FRANCISCO and CAMBRIDGE, Mass., Nov. 15, 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 treated in the Greater China portion of the global registrational Phase 3 ADDRESS study of efgartigimod in patients with pemphigus vulgaris (PV) or pemphigus foliaceus (PF).

ADDRESS is a randomized, double-blind, placebo-controlled, multi-center trial evaluating the safety and efficacy of efgartigimod in approximately 150 patients with PV or PF. Patients will include those newly diagnosed or currently experiencing flare that meet protocol-defined criteria. Patients will be randomized 2:1 to receive subcutaneous (SC) efgartigimod or placebo, both on top of prednisone.

“Pemphigus is a chronic, severe, and potentially life-threatening autoimmune disease of the skin 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. “We are excited about the therapeutic potential of efgartigimod in pemphigus, based on its mode of action in clearing IgGs. We look forward to advancing the China portion of this registrational Phase 3 study and to bringing such an innovative treatment option to patients with pemphigus in China.”

In a Phase 2 trial[1], efgartigimod was well-tolerated and exhibited an early effect on disease activity, as evidenced by a reduction in IgG and anti-desmoglein autoantibodies and an improvement in the Pemphigus Disease Area Index.

PV and PF are rare and severe autoimmune diseases where antibodies in the body attack skin proteins and cause blistering of the skin. PV is the most common type of pemphigus. In PV, the immune system produces IgG antibodies that mistakenly attack desmogleins 1 and 3, which are structures that hold skin and mucous cells together. This can cause skin and mucous cells to separate and fluid to collect between the layers of skin and mucous, forming blisters and ulcers. These lesions can cause severe pain, itching, and burning. In severe cases, there is significant sloughing of skin, with life-threatening fluid loss and great risk of infection. With PF, antibodies only attack desmoglein 1, which is only expressed in the skin. Therefore, blisters may appear on the scalp, face, or torso. It does not affect mucous membranes, so PF blisters will not appear in the mouth or eyes.

About Pemphigus in China

The prevalence of pemphigus in China is estimated at 90,000 patients. Current treatment options are limited, primarily corticosteroids and immunosuppressants. Several other treatments are sometimes used in combination with steroid medication and immunosuppressants, such as intravenous immunoglobulin or rituximab, if symptoms cannot be controlled. Despite the available treatment options, remission/relapse cycles are common, and there are safety concerns with long-term use. There remains a significant unmet need for innovative treatment options that provide early disease control and safe long-term responses.

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 pemphigus vulgaris, 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:

ZAI LAB CONTACTS:

Investor Relations: Ron Aldridge / Lina Zhang
+1 (781) 434-8465 / +86 136 8257 6943
ronald.aldridge@zailaboratory.com / lina.zhang@zailaboratory.com

Media: Danielle Halstrom / Xiaoyu Chen
+1 (215) 280-3898 / +86 185 0015 5011
danielle.halstrom@zailaboratory.com / xiaoyu.chen@zailaboratory.com

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[1] M Goebeler et al. Treatment of pemphigus vulgaris and foliaceus with efgartigimod, a neonatal Fc receptor inhibitor: a phase 2 multicentre, open-label feasibility trial. Accepted for publication. doi: 10.1111/bjd.20782

Source: Zai Lab Limited