Zai Lab Initiates Global Phase 2 Clinical Trial Evaluating ZL-1102 As a Topical Treatment for Chronic Plaque Psoriasis

May 22, 2024

This is the first compound in Zai's portfolio of internally developed drugs to advance into Phase 2, demonstrating Zai's global capabilities

Based on a proof-of-concept study, ZL-1102 is the first topical biologic to show penetration of psoriatic skin resulting in a clinical response

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 22, 2024-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced that the first patient has been dosed in a global Phase 2 clinical trial (NCT06380907) evaluating the efficacy and safety of the company's internally developed anti-IL-17 investigational therapy, ZL-1102, for the treatment of chronic plaque psoriasis (CPP). ZL-1102 is a novel human VH antibody fragment (Humabody®) targeting the IL-17 cytokine. Emphasizing its unique approach, ZL-1102 is being developed as a topical treatment for mild-to-moderate CPP, differentiating it from other anti-IL-17 products that target moderate-to-severe forms of the disease through systemic administration.

"This study marks an important milestone in Zai's evolution and is a testament to our outstanding internal R&D team's commitment to develop novel therapies to help patients across the globe," said Josh Smiley, President and Chief Operating Officer, Zai Lab.

"ZL-1102 is the first IL-17 targeted topical treatment in development for patients with less severe forms of CPP. Formulated to be applied directly to psoriatic skin lesions, we hope it can bypass unnecessary tissue exposure and avoid systemic toxicity commonly associated with intravenous or subcutaneous therapies," said Harald Reinhart, M.D., President and Head of Global Development, Neuroscience, Autoimmune & Infectious Diseases, Zai Lab. "ZL-1102 exemplifies the innovative, patient-focused R&D programs in our internal discovery and development pipeline. We aim to bring this novel treatment option to patients in need as quickly as possible."

Psoriasis affects about 125 million people worldwide; 80% to 90% of these individuals have plaque psoriasis and 70% to 80% of these cases are mild-to-moderate. Most systemic agents, i.e., oral and injectable medications, are prescribed for moderate-to-severe psoriasis. Zai Lab previously reported data from the proof-of-concept study in patients with mild-to-moderate CPP in which topical treatment with ZL-1102 showed a 45% relative improvement compared to placebo in the local Psoriasis Area Severity Index (PASI) score of the target lesion at four weeks, and consistently higher responder rates over time compared to placebo during and after the end of treatment.[1]

The Phase 2 global clinical trial of ZL-1102 is a randomized, double-blind, vehicle-controlled, dose-ranging study in patients with mild-to-moderate CPP. In this 5-arm trial, approximately 250 patients will receive topical therapy for 16 weeks. The primary endpoint is the proportion of patients achieving modified PASI75, which is at least a 75% reduction in the modified PASI score from baseline, at week 16. The study will also determine the efficacy of different doses of ZL-1102 compared to placebo at the end of therapy. Secondary objectives include efficacy throughout the treatment period, safety, tolerability, pharmacokinetics and anti-drug antibody (ADA). For more information about this trial, please visit https://clinicaltrials.gov/study/NCT06380907.

About ZL-1102

ZL-1102 is an investigational, novel human VH antibody fragment, targeting the IL-17A cytokine, formulated as a hydrogel for topical use in the treatment of chronic plaque psoriasis. Due to its small size and other features unique to this class of molecules, ZL-1102 has improved target affinity and tissue penetration compared to full-sized monoclonal antibodies. With potentially improved safety and tolerability, this topical therapeutic may bring the potential of IL-17-targeted treatments to the large patient population with less severe CPP.

About Mild-to-Moderate Chronic Plaque Psoriasis

Plaque psoriasis is a common chronic, systemic, inflammatory autoimmune skin disease characterized by red patches and plaques with silvery scales on the skin. Psoriasis affects approximately 125 million people worldwide. Plaque psoriasis is the most common type, affecting 80%-90% of those with psoriasis. 70–80% of plaque psoriasis cases are mild-to-moderate, and marketed IL-17 inhibitors are currently not indicated for such cases. Topical therapies are the standard of care for treatment of mild-to-moderate disease. However, current treatment options provide limited efficacy or have safety concerns with long-term use.

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 disease 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, 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 relating to our future expectations, plans, and prospects, including, without limitation, statements regarding the possible benefits, safety, and efficacy of ZL-1102; the treatment of chronic plaque psoriasis; and risks and uncertainties associated with drug development and commercialization. All statements, other than statements of historical fact, included in this press release are forward-looking statements, and can 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 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. We may not actually achieve the plans, carry out the intentions, or meet the expectations or projections disclosed in our forward-looking statements, and you should not place undue reliance on these 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 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) risks related to doing business in China, and (6) 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.

Notes:

(1) Sinclair, R., Sharifeh, S., Thackwray, S., Lickliter, J., Wu, J., Li, J., Qi, B., Bland-Ward, P., Reinhart, H. (2023). Topical application of a novel anti-interleukin-17A antibody fragment penetrates psoriasis skin: Results of a randomized, double-blind, placebo-controlled Phase IB study. June 28, 2023. https://pubmed.ncbi.nlm.nih.gov/37377276/

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Source: Zai Lab Limited