Zai Lab Announces Acceptance of New Drug Application for KarXT for the Treatment of Schizophrenia

January 17, 2025

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 17, 2025-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced that China's National Medical Products Administration (NMPA) has accepted the New Drug Application (NDA) for KarXT for the treatment of schizophrenia in adults.

"There are more than 8 million patients living with schizophrenia in China who face significant unmet needs due to the limited efficacy and undesirable side effects of current treatment options," said Dr. Rafael Amado, M.D., President, Head of Global Research and Development at Zai Lab. "In clinical trials, KarXT demonstrated statistically significant reductions of schizophrenia symptoms along with a tolerable safety profile. If approved, KarXT has the potential to redefine the treatment landscape."

"KarXT is the first new class of treatment for patients with schizophrenia in several decades," said Gang Wang, M.D., Dean of Beijing Anding Hospital, Capital Medical University and the leading principal investigator for the Phase 3 China study. "We are excited about this potentially transformative treatment option in clinical settings to benefit these patients as early as possible."

The NDA submission is supported by the results from a Phase 1 China Pharmacokinetics (PK) study, the Phase 3 China study (ZL-2701-001) and data from the global EMERGENT clinical programs.

The China Phase 3 study met its primary endpoint, with KarXT demonstrating a statistically significant 9.2-point difference from placebo in the reduction in the Positive and Negative Syndrome Scale (PANSS) total score from baseline at Week 5 (-16.9 KarXT vs. -7.7 placebo, p=0.0014). The study also met all key secondary efficacy endpoints, demonstrating a significant improvement in PANSS positive symptom subscale score, PANSS negative symptom subscale score, PANSS negative Marder factor score, the Clinical Global Impression-Severity (CGI-S) scale at week five and percentage of PANSS responders at week five compared to placebo. There were no safety signals that were new or unexpected in comparison with prior KarXT trials in schizophrenia. Similar to the global program, the common treatment emergent adverse events in the treatment arm include vomiting, tachycardia, nausea, systemic hypertension, dizziness and diarrhea.

In the global Phase 3 EMERGENT-2 and EMERGENT-3 trials, KarXT met its primary endpoint, demonstrating statistically significant reductions of schizophrenia symptoms compared to placebo. The safety and tolerability profile of KarXT has been established across acute and long-term trials.

In September 2024, the U.S. Food and Drug Administration (FDA) approved COBENFY™ (xanomeline and trospium chloride) for the treatment of schizophrenia in adults. COBENFY does not have atypical antipsychotic class warnings and precautions and does not have a boxed warning.

About KarXT

KarXT (xanomeline and trospium chloride) is a combination of an oral M1/M4-preferring muscarinic acetylcholine receptor agonist and a muscarinic acetylcholine receptor antagonist. This combination is in development for the treatment of psychiatric conditions, including schizophrenia and Alzheimer's-related psychosis. Xanomeline stimulates muscarinic receptors in the central nervous system implicated in these conditions, as compared to current antipsychotic medicines, which mostly target dopamine or serotonin receptors.

Zai Lab has an exclusive license from Karuna Therapeutics, Inc., a company acquired by Bristol Myers Squibb, to develop, manufacture, and commercialize KarXT in Greater China (mainland China, Hong Kong, Macau, and Taiwan, collectively).

About Schizophrenia

Schizophrenia is a persistent and often disabling mental illness affecting how a person thinks, feels, and behaves. It is characterized by positive symptoms (e.g., hallucinations and delusions), negative symptoms (e.g., difficulty enjoying life and withdrawal from others), and cognitive impairment (e.g., deficits in memory, concentration, and decision-making) – all of which can severely impact functioning, with only 10% of patients gainfully employed and many struggling to meet adult milestones, such as living independently. The life expectancy of people living with schizophrenia is reduced by 10-20 years compared to the general population. Schizophrenia affects nearly 24 million people worldwide and is most commonly treated with antipsychotics. Unfortunately, many people with schizophrenia continue to experience limited efficacy or problematic side effects while on current antipsychotic therapy, and approximately 75% of patients discontinue medication before 18 months. When schizophrenia treatment is discontinued, it can lead to impacts on health including relapse, hospitalization, and longer time to remission.

More than 8 million people in China are living with schizophrenia, yet fewer than half are receiving treatment, and even fewer are obtaining adequate symptom improvement using the current treatment of antipsychotics. Like patients globally, there is a significant need for more effective therapies with improved safety to treat patients with schizophrenia in Greater China.

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, immunology, neuroscience and infectious disease. Our goal is to leverage our competencies and resources to

positively impact human health 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 prospects of and plans for developing and commercializing KarXT, the potential benefits of KarXT, and the potential treatment of schizophrenia and other psychiatric and neurological conditions including Alzheimer's-related psychosis. These forward-looking statements may contain 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. 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 decisions, (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. 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20250117029564/en/

For more information, please contact:

Investor Relations:
Christine Chiou / Lina Zhang
+1 (917) 886-6929 / +86 136 8257 6943
christine.chiou1@zailaboratory.com / lina.zhang@zailaboratory.com

Media:
Shaun Maccoun / Xiaoyu Chen
+1 (857) 270-8854 / +86 185 0015 5011
shaun.maccoun@zailaboratory.com / xiaoyu.chen@zailaboratory.com

Source: Zai Lab Limited