Zai Lab Announces Approval of COBENFY (xanomeline and trospium chloride) in China, a First-in-Class Therapy for Schizophrenia

December 23, 2025

COBENFY is the first major advance in schizophrenia treatment in decades, offering a novel mechanism of action distinct from other therapies

COBENFY has already been included in China's national-level schizophrenia treatment guidelines, underscoring the urgent need for new therapeutic options in China

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Dec. 23, 2025-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced that China's National Medical Products Administration (NMPA) approved the New Drug Application (NDA) for COBENFY® (xanomeline and trospium chloride) for the treatment of schizophrenia in adults. COBENFY is the first schizophrenia therapy with a novel mechanism of action approved in over 70 years [1], offering a fundamentally new approach to treating schizophrenia. By selectively activating M1 and M4 receptors in the brain, COBENFY addresses core disease pathways beyond traditional dopamine-blocking antipsychotics.

Schizophrenia is a chronic and often disabling mental health disorder affecting how a person thinks, feels, and behaves. It is characterized by three core symptom domains including positive symptoms (e.g., hallucinations and delusions), negative symptoms (e.g., deficits in motivation, pleasure and social withdrawal), and cognitive impairment (e.g., deficits in memory, concentration, and decision-making). In China, despite the availability of antipsychotic therapies, many patients experience inadequate improvement across symptom domains and intolerable side effects.

"We are pleased to receive NMPA approval for COBENFY, marking a groundbreaking milestone for schizophrenia care in China," said Rafael G. Amado, M.D., President, Head of Global Research and Development at Zai Lab. "Approximately 8 million [2] adults in China are living with schizophrenia, many of whom continue to struggle with persistent symptoms or challenging side effects from existing therapies. With its broad symptom improvement and unique safety profile, COBENFY has the potential to redefine how schizophrenia can be managed, and we look forward to bringing this transformative therapy to patients as soon as possible."

"COBENFY represents the first truly new therapeutic approach for schizophrenia in decades," said Prof. Gang Wang, M.D., Dean of Beijing Anding Hospital, Capital Medical University and the leading principal investigator for the Phase 3 China study. "COBENFY has demonstrated comprehensive improvement across positive, negative and cognitive symptoms, while avoiding many of the adverse effects commonly associated with traditional antipsychotics, including weight gain, hyperprolactinemia, and a problematic movement disorder called extrapyramidal symptoms, offering a meaningful new option for patients."

The NMPA's approval of COBENFY is supported by the results from a Phase 1 pharmacokinetics (PK) study conducted in China, the Phase 3 China study (ZL-2701-001), and data from three global EMERGENT clinical studies.

In September, the Chinese Medical Association released the "China Schizophrenia Prevention and Treatment Guidelines (2025 Edition)" which included COBENFY as a novel treatment. This is the first national-level guideline to include COBENFY.

[1] Kingwell, K. (2024). Muscarinic drugs breathe new life into schizophrenia pipeline. Nature Reviews Drug Discovery, 23(9), 647–649. https://doi.org/10.1038/d41573-024-00129-w

[2] Huang, Y., Wang, Y., Wang, H., Liu, Z., Yu, X., Yan, J., Yu, Y., Kou, C., Xu, X., Lu, J., Wang, Z., He, S., Xu, Y., He, Y., Li, T., Guo, W., Tian, H., Xu, G., Xu, X., … Wu, Y. (2019). Prevalence of mental disorders in China: A cross-sectional epidemiological study. The Lancet Psychiatry, 6(3), 211–224. https://doi.org/10.1016/S2215-0366(18)30511-X

About COBENFY

COBENFY (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. 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. Trospium does not appreciably cross the blood-brain barrier and acts peripherally to mitigate xanomeline-induced peripheral cholinergic adverse events.

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

About Schizophrenia

Schizophrenia is a chronic and often disabling mental health disorder affecting how a person thinks, feels, and behaves. It is characterized by three

core symptoms including positive symptoms, negative symptoms and cognitive impairment – 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 a healthy 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 in negative symptoms as well as cognitive symptoms or problematic side effects including weight gain, hyperprolactinemia, and a problematic movement disorder called extrapyramidal symptoms while on current antipsychotic therapy. Due to these problems, approximately 75% of patients discontinue medication before 18 months. When schizophrenia treatment is discontinued, it can adversely impact patient health including relapse, hospitalization, and longer time to remission.

Approximately 8 million adults in mainland China are living with schizophrenia, yet few are obtaining adequate symptom improvement with the current treatment using antipsychotics. Like patients globally, there is a significant need for more comprehensive effective therapies with improved safety to treat patients with schizophrenia in Greater China.

About Zai Lab

Zai Lab Limited (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.

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 COBENFY, the potential benefits of COBENFY, and the potential treatment of schizophrenia and other psychiatric and neurological conditions. 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.

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