



Zai Lab and Karuna Therapeutics Announce Strategic Collaboration for Development, Manufacturing, and Commercialization of KarXT in Greater China

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Zai Lab obtains exclusive rights to develop and commercialize KarXT in Greater China

Karuna to receive upfront cash payment of \$35 million, up to \$152 million in potential near- and long-term development and commercial milestones and other payments, and low-double-digit to high-teens tiered royalties

BOSTON and SHANGHAI and SAN FRANCISCO, Nov. 09, 2021 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), a patient-focused, innovative, commercial-stage, global biopharmaceutical company, and Karuna Therapeutics, Inc. (NASDAQ: KRTX), a clinical-stage biopharmaceutical company driven to create and deliver transformative medicines for people living with psychiatric and neurological conditions, today announced their entry into an exclusive license agreement for the development, manufacturing, and commercialization of KarXT (xanomeline-trospium) in Greater China, including mainland China, Hong Kong, Macau, and Taiwan.

KarXT is an oral, investigational M1/M4-preferring muscarinic agonist that stimulates receptors in the central nervous system implicated in various psychiatric conditions. KarXT was designed to unlock the therapeutic potential of xanomeline, which demonstrated significant benefits in reducing symptoms of psychosis in Phase 2 studies in schizophrenia and Alzheimer's disease, while ameliorating side effects seen in earlier studies. In the Phase 2 EMERGENT-1 trial, KarXT demonstrated clinically meaningful and statistically significant improvements in the primary endpoint of Positive and Negative Syndrome Scale (PANSS) total score, and in key secondary endpoints, including PANSS-positive subscore and PANSS-negative subscore, at week 5, and was generally well-tolerated.

Karuna is evaluating KarXT in late-stage clinical trials for the treatment of schizophrenia and psychosis in Alzheimer's disease. The EMERGENT program, the clinical program evaluating KarXT for the treatment of schizophrenia, is underway. The EMERGENT program is comprised of the previously completed Phase 2 EMERGENT-1 trial and four ongoing Phase 3 trials, with data from EMERGENT-2 and EMERGENT-3, the two Phase 3 acute efficacy and safety trials, expected in mid-2022 and in the second half of 2022, respectively. Karuna plans to initiate the Phase 3 ARISE trial evaluating KarXT as an adjunctive treatment for schizophrenia in adults who inadequately respond to atypical antipsychotics in the fourth quarter of 2021. Additionally, Karuna also plans to initiate a Phase 3 program evaluating KarXT for the treatment of psychosis in Alzheimer's disease in mid-2022 following encouraging results from the completed Phase 1b healthy elderly volunteer trial, which suggest that potentially therapeutic doses of KarXT can be administered to elderly adults while maintaining a favorable tolerability profile. Zai Lab will work with Karuna to design the optimal strategy to accelerate the development and regulatory timeline of KarXT in Greater China.

Under the terms of the agreement, Karuna will receive a \$35 million upfront payment and is eligible to receive up to an additional \$80 million in development and regulatory milestones. Karuna is also eligible to receive up to \$72 million in sales milestones and low-double-digit to high-teens tiered royalties based on annual net sales of KarXT in Greater China. Zai Lab will fund substantially all development, regulatory, and commercialization activities in Greater China.

"We are thrilled to collaborate with Zai Lab, who shares our commitment to bringing transformative medicines to people living with psychiatric conditions globally," said Steve Paul, M.D., chief executive officer, president, and chairman of Karuna Therapeutics. "With their proven record of successfully developing and commercializing novel therapies in Greater China, we believe that Zai Lab is the ideal partner to expand the global footprint for KarXT alongside our ongoing efforts in the U.S., with the goal of providing meaningful treatments to millions of people living with mental illness globally."

"Our collaboration with Karuna is a significant milestone for Zai Lab, marking the expansion and diversification of our development and commercial portfolio into neuroscience, our fourth therapeutic area," said Samantha Du, Ph.D., founder, chairperson and chief executive officer of Zai Lab. "KarXT is well positioned to serve as the anchor asset in our new neuroscience franchise. Zai Lab's mission is to deliver innovative medicines to address unmet medical needs of patients, and we look forward to working with Karuna to bring KarXT to patients in need in Greater China as soon as possible."

"There is a significant need for new and more effective therapies with improved safety to treat serious psychiatric conditions in Greater China," said Gang Wang, M.D., Director of National Clinical Research Center for Mental Disorders, Dean of Beijing Anding Hospital, Capital Medical University. "Currently, more than 8 million people in Greater China are living with schizophrenia, yet fewer than half are receiving treatment, and even fewer are obtaining adequate symptom improvement from current treatment. We believe KarXT has the potential to provide a meaningful new treatment option for many patients living with schizophrenia and other conditions with disabling symptoms of psychosis."

Goldman Sachs & Co. LLC is acting as financial advisor to Karuna Therapeutics.

About KarXT

KarXT (xanomeline-trospium) is an oral, investigational M1/M4-preferring muscarinic acetylcholine receptor agonist in development for the treatment of psychiatric and neurological conditions, including schizophrenia and dementia-related psychosis. KarXT preferentially stimulates muscarinic receptors in the central nervous system implicated in these conditions, as opposed to current antipsychotic medicines, which bind to the D₂ dopamine receptor. KarXT has the potential to usher in a new class of treatment for schizophrenia and dementia-related psychosis based on its differentiated mechanism of action.

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.

About Karuna Therapeutics

Karuna Therapeutics is a clinical-stage biopharmaceutical company driven to create and deliver transformative medicines for people living with psychiatric and neurological conditions. At Karuna, we understand there is a need for differentiated and more effective treatments that can help patients navigate the challenges presented by these severe and disabling disorders. Utilizing our extensive knowledge of neuroscience, we are harnessing the untapped potential of the brain in pursuit of novel pathways to develop medicines that make meaningful differences in peoples' lives. For more information, please visit www.karunatx.com.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects, including, without limitation, statements relating to the potential, benefits, safety and efficacy of KarXT; the clinical development of KarXT; the potential treatment of schizophrenia and dementia-related psychosis; the potential of Zai Lab's commercial business and pipeline programs; the anticipated benefits and potential of Zai Lab's collaboration arrangement with Karuna Therapeutics, Inc. and other risks and uncertainties associated with drug development and commercialization. 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 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) our 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.

Karuna Therapeutics Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding the potential benefits and results that may be achieved through our collaboration with Zai Lab, our ongoing and planned clinical trials and regulatory filings, our goals to develop and commercialize our product candidates, and other statements identified by words such as "could," "expects," "intends," "may," "plans," "potential," "should," "will," "would," or similar expressions and the negatives of those terms. Forward-looking statements are not promises or guarantees of future performance and are subject to a variety of risks and uncertainties, many of which are beyond our control, and which could cause actual results to differ materially from those contemplated in such forward-looking statements. These factors include risks related to our limited operating history, our ability to obtain necessary funding, our ability to generate positive clinical trial results for our product candidates and other risks inherent in clinical development, the timing and scope of regulatory approvals, changes in laws and regulations to which we are subject, competitive pressures, risks relating to business interruptions resulting from the coronavirus (COVID-19) pandemic, and other risks set forth under the heading "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2020. Our actual results could differ materially from the results described in or implied by such forward-looking statements. Forward-looking statements speak only as of the date hereof, and, except as required by law, we undertake no obligation to update or revise these forward-looking statements.

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