Karuna Therapeutics Announces U.S. Food and Drug Administration Accepts New Drug Application for KarXT for the Treatment of Schizophrenia

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Prescription Drug User Fee Act (PDUFA) action date is September 26, 2024

If approved, KarXT would represent the first new pharmacological approach to treating schizophrenia in several decades

The application is supported by positive data from the EMERGENT clinical trial program showing KarXT is associated with significant improvements in schizophrenia symptoms

BOSTON--(BUSINESS WIRE)--Nov. 29, 2023-- Karuna Therapeutics, Inc. (NASDAQ: KRTX), a biopharmaceutical company driven to discover, develop, and deliver transformative medicines for people living with psychiatric and neurological conditions, today announced the U.S. Food and Drug Administration (FDA) has accepted its New Drug Application (NDA) for KarXT (xanomeline-trospium) for the treatment of schizophrenia in adults. The application has been granted a Prescription Drug User Fee Act (PDUFA) date of September 26, 2024.

“We are pleased the NDA for KarXT has been accepted, and we look forward to working with the FDA during the review process,” said Bill Meury, president and chief executive officer of Karuna Therapeutics. “There is a significant need for new treatment options for serious mental illness. If approved, KarXT could be one of the more important new product introductions in neuropsychiatry by providing a novel pharmacological approach for the treatment of schizophrenia.”

“Schizophrenia’s disabling symptoms pose significant challenges to navigating crucial aspects of life, including developing relationships, maintaining employment, and securing safe housing,” said Gordon Lavigne, M.Ed., chief executive officer, Schizophrenia & Psychosis Action Alliance. “Diagnosis marks the beginning of an often long and tiresome search for effective and tolerable treatment options. The nature and magnitude of side effects often play a pivotal role in whether someone continues treatment, which is often crucial to minimize the risk of relapse and realize the life-altering benefits of long-term treatment. Potential approval of a pharmacologically distinct treatment option would be a welcome innovation for people living with schizophrenia.”

The NDA submission is supported by efficacy and long-term safety data from the EMERGENT program, the clinical program evaluating KarXT as a treatment for schizophrenia. The EMERGENT program includes the three completed positive EMERGENT-1, EMERGENT-2, and EMERGENT-3 trials evaluating the efficacy and safety of KarXT compared to placebo, and the EMERGENT-4 and EMERGENT-5 trials evaluating the long-term safety of KarXT.

In all three placebo-controlled trials, KarXT met its primary endpoint, demonstrating statistically significant and clinically meaningful improvements in symptoms of schizophrenia compared to placebo as measured by Positive and Negative Syndrome Scale (PANSS) total score. KarXT was found to be generally well tolerated, with the most common adverse events being cholinergic in nature and mild to moderate in severity. Notably, KarXT was not associated with common side effects of currently available antipsychotics, including weight gain, somnolence, and movement disorders.

“KarXT focuses on a novel pathway through muscarinic receptors to indirectly modulate dopamine signaling in key brain circuits, and in clinical trials completed to date KarXT has demonstrated the much-needed combination of strong tolerability and clinically meaningful symptom reduction,” remarked Rishi Kakar, M.D., chief scientific officer and medical director of Segal Trials, and investigator in the EMERGENT program. “This decision by the FDA marks an important step in working toward a new chapter in the standard of care for those facing the immense, daily struggle of this serious mental illness.”

About KarXT

KarXT (xanomeline-trospium) is an investigational muscarinic antipsychotic in development for the treatment of schizophrenia and psychosis related to Alzheimer’s disease. Through its novel mechanism of action, KarXT acts as a dual M1/M4 muscarinic acetylcholine receptor agonist in the central nervous system, which is thought to improve positive, negative, and cognitive symptoms of schizophrenia. Unlike existing treatments, KarXT does not directly block dopamine receptors, representing a potential new approach to treating schizophrenia.

About Schizophrenia

Schizophrenia is a persistent and often disabling mental illness impacting how a person thinks, feels, and behaves, and affects nearly 24 million people worldwide, including 2.8 million people in the U.S. It is characterized by three symptom domains: positive symptoms (hallucinations and delusions), negative symptoms (difficulty enjoying life and withdrawal from others), and cognitive impairment (deficits in memory, concentration, and decision-making). In part due to limitations with current treatments, people living with schizophrenia often struggle to maintain employment, live independently, and manage relationships. While current treatments can be effective in managing select symptoms, approximately 30% of people do not respond to therapy, with an additional 50% experiencing only a partial improvement in symptoms or unacceptable side effects.

About Karuna

Karuna Therapeutics is a biopharmaceutical company driven to discover, develop, 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 serious mental illness. 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.

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 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, our ability to identify additional product candidates, risks relating to business interruptions, and other risks set forth under the heading "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2022 and in our subsequent filings with the Securities and Exchange Commission. 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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