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| CLIENT: | Segal Trials |  |
| PROJECT: | Release, Segal Trials Plays Pivotal Role In Karuna Therapeutics Submitting New Drug Application (NDA) to the U.S. Food & Drug Administration (FDA) | |
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**MIAMI-BASED CLINICAL TRIAL COMPANY**

**PARTICIPATION IN STUDY SHOWS POSITIVE RESULTS FROM PHASE 3  
EMERGENT-2 KarXT IN SCHIZOPHRENIA**

***Segal Trials Plays Pivotal Role In Karuna Therapeutics Submitting New Drug Application to the U.S. Food & Drug Administration (FDA)***

MIAMI, FL (August <XX>, 2022) – Segal Trials, a privately held network of clinical research sites throughout South Florida has concluded a phase 3 EMERGENT-2 trial with Karuna Therapeutics. The study focused on evaluating the efficacy, safety, and tolerability of its lead investigational therapy, KarXT (xanomeline-trospium), in adults with schizophrenia. The study was overseen by Segal Trials, Chief Scientific Officer, & Principal Investigator, Rishi Kakar, MD.

“Despite the number of available treatment options, there continues to be a tremendous unmet need in the treatment of schizophrenia, placing an immense burden on both patients and their caregivers,” said Rishi Kakar, M.D., chief scientific officer, Segal Trials and lead investigator of the Phase 3 EMERGENT-2 trial. “This data builds on the growing body of clinical evidence supporting the potential of KarXT as a new and differentiated approach for schizophrenia, demonstrating notable improvements across both positive and negative symptoms, while not being associated with common problematic side-effects of current therapies, such as weight gain, sedation and movement disorders. This unique profile of KarXT has the potential to provide a new meaningful treatment option for our patients and their families beyond the current standard of care.”

Due to the success of the clinical trial, Karuna Therapeutics plans to submit a New Drug Application (NDA) with the U.S. Food & Drug Administration (FDA) in mid-2023. Marking another monumental milestone for Segal Trials, adding another possible FDA approval to the more than 56+ already approved indications the company has participated in.

About Schizophrenia

Schizophrenia is a chronic and often debilitating mental illness that impacts how one thinks, feels, and behaves. It is characterized by positive symptoms (hallucinations and delusions), negative symptoms (difficulty enjoying life and withdrawal from others), and cognitive impairment. Together these symptoms can severely impact quality of life and productivity, with only 10% of people 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 approximately 21 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 antipsychotic therapy, and up to 74% 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.

For more information about Segal Trials, or to schedule an interview, please contact Tabatha Cirgenski at [tcirgenski@SegalTrials.com](mailto:tcirgenski@SegalTrials.com).

# About Segal Trials

[Segal Trials](https://www.segaltrials.com/), founded in 1998, is a privately held network of research sites throughout South Florida conducting Phase I-IV research trials that have led to 56 FDA-approved medications and devices. The company’s trials focus on psychiatry, neurology, addiction, insomnia, infectious diseases, vaccine development, and women’s health; and it runs trials in outpatient, inpatient, PSG, and residential care facility settings.

**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 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.

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