

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of Earliest Event Reported): June 23, 2021

KARUNA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38958
(Commission
File Number)

27-0605902
(I.R.S. Employer
Identification No.)

99 High Street, Floor 26
Boston, Massachusetts
(Address of principal executive offices)

02110
(Zip Code)

Registrant's telephone number, including area code: (857) 449-2244

Not Applicable

Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.0001	KRTX	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Results of Operations and Financial Condition

On June 23, 2021, Karuna Therapeutics, Inc. (the “Company”) announced the results of its Phase 1b clinical trial evaluating the safety and tolerability of KarXT in healthy elderly volunteers. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information in this Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 [Press Release issued by Karuna Therapeutics, Inc., dated June 23, 2021](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: June 23, 2021

KARUNA THERAPEUTICS, INC.

By: /s/ Troy Ignelzi
Troy Ignelzi
Chief Financial Officer



Karuna Therapeutics Announces Results from Phase 1b Trial Evaluating the Safety and Tolerability of KarXT in Healthy Elderly Volunteers

Company to initiate a Phase 2 trial evaluating KarXT in dementia-related psychosis in the first half of 2022

Results suggest that KarXT can be administered to elderly volunteers at doses which achieve xanomeline blood levels similar to those reported in the Phase 2 EMERGENT-1 trial in adults with schizophrenia while maintaining a favorable tolerability profile

The majority of healthy elderly volunteers in the Phase 1b trial were titrated to xanomeline doses of 150 to 200 mg when dosed with KarXT

Safety and tolerability profile in Phase 1b trial in healthy elderly volunteers consistent with prior trials of KarXT

BOSTON—June 23, 2021— 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 data from its completed Phase 1b trial evaluating the safety and tolerability of KarXT (xanomeline-trospium) in healthy elderly volunteers. The Company had previously announced a preliminary analysis of data from the first two cohorts in the trial earlier this year. Based on results from the Phase 1b trial in healthy elderly volunteers, the Company plans to initiate a Phase 2 trial evaluating KarXT in dementia-related psychosis in the first half of 2022.

The placebo-controlled, inpatient Phase 1b dose-ranging trial consisted of three cohorts, each enrolling 16 healthy elderly volunteers, randomized 3:1 to receive KarXT or placebo. As part of the flexible dosing protocol, a volunteer's dose was increased if they were tolerating KarXT well at the time of the potential dose increase, as determined by a clinician. In the trial, the majority of healthy elderly volunteers were titrated to xanomeline doses of 150 to 200 mg when dosed with KarXT three times per day. As previously reported, pharmacokinetic data from Cohorts 1 and 2 demonstrated that healthy elderly volunteers achieved mean xanomeline blood levels comparable to, or slightly higher than, the mean xanomeline blood levels reported in the Phase 2 EMERGENT-1 trial evaluating KarXT in adults with schizophrenia. The Company plans to evaluate pharmacokinetic data from Cohort 3, once available. Previous trials of KarXT have demonstrated that the current formulation of KarXT results in xanomeline exposures, or blood levels, that are approximately 10% greater than blood levels seen in earlier trials of xanomeline alone.

The treatment-related adverse events (AEs) were similar to those observed in prior trials of KarXT, and a majority (>80%) were rated mild in severity. One serious AE of urinary retention was reported in Cohort 1. The Company believes the report of urinary retention was related to a higher dose of trospium used in Cohort 1 compared to doses used in Cohorts 2 and 3, where urinary retention was not observed. No serious or severe AEs were observed in Cohorts 2 and 3. Consistent with prior trials of KarXT, blood pressure in healthy elderly volunteers receiving KarXT was similar to placebo, and no syncopal events were observed. Heart rate increases observed in the trial were also consistent with prior trials of KarXT.

Data from the Phase 1b trial suggest that a lower dose ratio of trospium to xanomeline, compared to the ratios used in Phase 1 trials in healthy adult volunteers and in the Phase 2 EMERGENT-1 trial evaluating KarXT in adults with schizophrenia, was better tolerated by healthy elderly volunteers.

“We are encouraged that the data from our Phase 1b healthy elderly volunteers trial suggest that potentially therapeutic doses of KarXT can be administered to elderly adults while maintaining a favorable tolerability profile,” said Stephen Brannan, M.D., chief medical officer of Karuna Therapeutics. “Results from the third cohort provide additional data as we finalize the dosing and titration protocol for our Phase 2 trial in dementia-related psychosis.”

“The results from the Phase 1b trial in healthy elderly volunteers, as well as a prior Phase 2 study demonstrating the potential of xanomeline to treat and prevent psychosis in patients with Alzheimer’s disease, give us confidence in the potential utility of KarXT for the treatment of dementia-related psychosis,” added Steve Paul, M.D., chief executive officer, president and chairman of the board of Karuna Therapeutics. “These results support the progression of KarXT into a Phase 2 clinical trial for the treatment of dementia-related psychosis, which we plan to commence in the first half of 2022.”

About KarXT

KarXT, a proprietary oral modulator of muscarinic cholinergic receptors, is Karuna’s lead product candidate. It combines xanomeline, a novel muscarinic agonist, with trospium, an FDA-approved muscarinic antagonist that does not appreciably cross the blood-brain-barrier, to preferentially stimulate muscarinic receptors in the central nervous system. This novel product candidate, if approved, has the potential to usher in a new treatment paradigm and dramatically impact patients with schizophrenia and other psychotic disorders by providing a differentiated mechanism of action relative to current D2 dopamine and serotonin receptor-targeting antipsychotic drugs.

About Karuna

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.

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 expectations about the timing of advancing of our 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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