



Recursion Presents Phase 2 Data for REC-994 in CCM in Late-Breaking Oral Presentation at the International Stroke Conference

February 5, 2025

- Met primary endpoint of safety and tolerability in CCM patients with no treatment-related discontinuations or Grade 3 adverse events
- In comparison to placebo, treatment with REC-994 400 mg showed promising signals in both MRI-based lesion volume reduction and functional outcome as measured by changes in the modified Rankin scale (mRS) score
- In patients with cavernomas located in the brainstem, a subset of patients with significant unmet need, decreases in mean absolute total lesion volume and improvements in mRS scores with REC-994 400 mg were also observed
- Next steps will be guided by regulatory discussions and on-going long term extension study

SALT LAKE CITY, Feb. 05, 2025 (GLOBE NEWSWIRE) -- Recursion (Nasdaq: RXRX) reported 12 month data from the Phase 2 study (SYCAMORE) of REC-994, the first industry sponsored Phase 2 trial completed in Cerebral Cavernous Malformations (CCM). The Company announced in September 2024 that the signal-finding study [met its primary endpoint](#).

These results were presented today at the [Late-Breaking Science Concurrent Oral Abstract Sessions](#) at the International Stroke Conference (ISC) in Los Angeles, CA. Recursion will also hold a webinar on Thursday, February 6th at 6:30am MT/8:30am ET/1:30pm GMT to present the Phase 2 data. The webinar will be broadcast from Recursion's X (formerly Twitter), LinkedIn, and YouTube accounts with an opportunity to submit questions [here](#). The full presentation can be accessed after the webinar on Recursion's events & presentation [page](#).

"The results of the SYCAMORE trial demonstrate safety of REC-994 for CCM patients and promising trends of efficacy including 50% of patients achieving a reduction in mean lesion volume after 12 months of treatment *and* improved functional outcome as assessed by mRS at the 400 mg dose. My co-investigators and I are encouraged by these initial findings and we look forward to continued work with Recursion on the REC-994 program," said Dr. Jan-Karl Burkhardt, MD, Division Head, Cerebrovascular Surgery, University of Pennsylvania and Principal Investigator of the study.

"We are pleased to share the updated Phase 2 data through a late-breaking oral presentation at this year's International Stroke Conference. These preliminary results show promising MRI-based and functional outcome signals, and we look forward to continued discussions with the FDA, and the CCM scientific and patient communities on next steps," said Najat Khan, Ph.D., Chief R&D Officer and Chief Commercial Officer of Recursion.

As the first industry-initiated trial in CCM, the SYCAMORE study was designed to evaluate safety as well as efficacy signals with broad patient populations. The trial was not powered to demonstrate statistical difference against placebo, and patients were not stratified or enriched across dose levels.

REC-994 SYCAMORE Phase 2 Trial Results

Safety & Tolerability (primary endpoint)

- No safety signals observed, with incidence of adverse events comparable between treatment and placebo arms
- Most common adverse events reported in at least 10% of participants included: Covid-19, dizziness, headache, back pain, and constipation
 - No SAEs related to study drug
 - Majority of TEAEs were Grade 1-2
 - No treatment-related adverse events that led to discontinuations

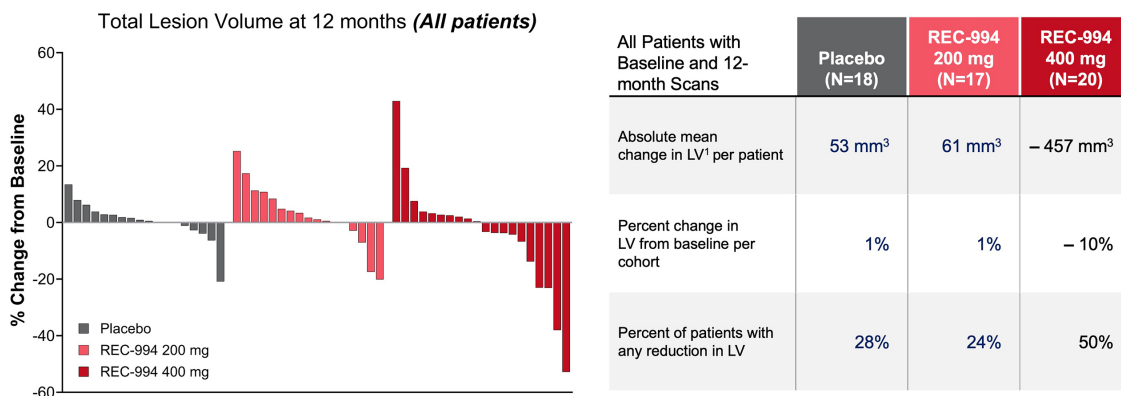
| Event, n (%) | Placebo (N=20) | REC-994 200 mg (N=21) | REC-994 400 mg (N=21) | Total (N=62) |
|--|------------------|-----------------------|-----------------------|------------------|
| Any Treatment Emergent Adverse Event (TEAE) | 17 (85.0) | 18 (85.7) | 15 (71.4) | 50 (80.6) |
| TEAEs Grade ≥3 | 4 (20.0) | 7 (33.3) | 3 (14.3) | 14 (22.6) |
| Any TEAE related to study drug¹ | 2 (10.0) | 0 | 5 (23.8) | 7 (11.3) |
| Grade ≥3 TEAE | 0 | 0 | 0 | 0 |
| Discontinuation due to TEAE | 0 | 0 | 0 | 0 |
| Dose interruption due to TEAE | 0 | 0 | 0 | 0 |

¹In the REC-400 mg arm these consisted of dizziness, rash, anemia, nausea and peripheral edema. In the placebo arm these consisted of dizziness and erythema multiforme. Across both arms, TEAEs related to study drug were Grade 1 or 2.

Select Secondary & Exploratory Analyses

• Total Cerebral Lesion Volume

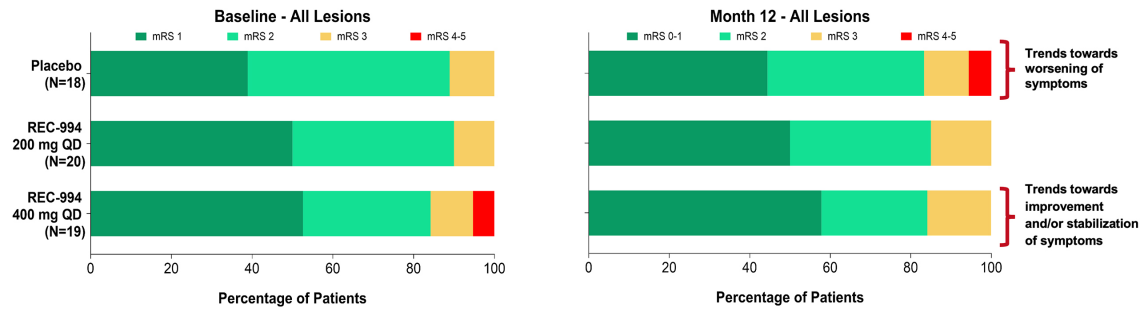
- After 12 months of treatment, 50% of patients on REC-994 400 mg (N=20) demonstrated reduction in total lesion volume (LV) versus 28% observed in placebo (N=18). Patients on REC-994 200 mg (N=17) had similar changes in lesion volume compared to placebo
- An absolute mean decrease in total lesion volume of -457 mm^3 was observed in the 400 mg arm vs. an absolute mean increase of 61 mm^3 and 53 mm^3 in the 200 mg and placebo arms, respectively



¹Analysis of change from baseline between treatment and placebo for change in lesion volume (LV) at month 12 for REC-994 200 mg (p=0.912) and REC-994 400 mg (p=0.089) assessed by mixed model for repeated measures (MMRM) analysis

• Modified Rankin Scale (mRS) scores

- The modified Rankin Scale (mRS) is widely recognized and approved by the FDA as a clinically meaningful endpoint for assessing functional outcomes in acute stroke trials. A single point change on the mRS is clinically relevant, with precedent for the FDA accepting dichotomous approaches using mRS cutoffs
- At baseline, patients on REC-994 400 mg had a greater proportion of mRS scores ≥ 3, including an mRS score of 4-5, indicating that at the start of study these patients had worse clinical function versus the placebo arm
- After 12 months of treatment, patients on REC-994 400 mg demonstrated trends toward improvement and/or stabilization of symptoms versus the placebo arm, which observed trends towards functional decline



1. Broderick et al, Stroke (2017)

• Brainstem Cohort

- Similar trends in lesion volume reduction and improvement or stabilization as assessed by mRS in the 400 mg REC-994 arm were seen in patients with brainstem lesions
- These observations support further investigation in a population of high unmet need, as cavernomas located in the brainstem are not amenable to surgical intervention

Additional secondary and exploratory analyses

- Time-dependent reductions in hemosiderin ring size observed in the 400 mg arm as compared to 200 mg and placebo
- Seizure frequency appeared to be reduced in the 400 mg arm as compared to 200 mg and placebo however, there was imbalance with respect to seizure history and frequency across the arms
- Incidence of new symptomatic hemorrhage events were comparable across arms and in line with natural history studies
- Other PROs including PROMIS29, CCM-HI, NIHSS, SMSS, CGI, and PGI did not demonstrate differences between the treatment arms of the study nor placebo

Next steps

Recursion intends to submit these data for publication in a peer reviewed scientific journal. Next steps will be guided by regulatory discussions and on-going long term extension study.

About REC-994

REC-994 is an orally bioavailable, superoxide scavenger small molecule under development for the treatment of symptomatic CCM. The potential of REC-994 in CCM was demonstrated using the earliest version of what would become the foundational technology underlying the Recursion OS. Subsequently, REC-994 demonstrated preclinical activity in models for CCM and tolerability and suitability for chronic dosing in [Phase 1](#) single ascending dose escalation (SAD) and multiple ascending dose escalation (MAD) trials in healthy volunteers directed and executed by Recursion. Recursion received Orphan Drug Designation for REC-994 in symptomatic CCM in the US and Europe.

About the SYCAMORE Trial

Our Phase 2 SYCAMORE clinical trial is a randomized, double-blind, placebo-controlled study of two doses (200 mg and 400 mg) of REC-994 in participants with CCM. The primary endpoint of the study is safety and tolerability. Secondary efficacy endpoints include MRI-based endpoints, clinician and patient reported outcomes, as well as selected biomarkers. This trial was fully enrolled in June 2023 with 62 participants, and 80% of participants who completed 12 months of treatment have entered the long-term extension study. This signal-finding study was not powered to demonstrate statistical significance.

About Recursion

Recursion (NASDAQ: RXX) is a clinical stage TechBio company leading the space by decoding biology to radically improve lives. Enabling its mission is the Recursion OS, a platform built across diverse technologies that continuously generate one of the world's largest proprietary biological and chemical datasets. Recursion leverages sophisticated machine-learning algorithms to distill from its dataset a collection of trillions of searchable relationships across biology and chemistry unconstrained by human bias. By commanding massive experimental scale — up to millions of wet lab experiments weekly — and massive computational scale — owning and operating one of the most powerful supercomputers in the world, Recursion is uniting technology, biology and chemistry to advance the future of medicine.

Recursion is headquartered in Salt Lake City, where it is a founding member of BioHive, the Utah life sciences industry collective. Recursion also has offices in Toronto, Montréal, New York, London, Oxford area, and the San Francisco Bay area. Learn more at www.Recursion.com, or connect on X (formerly Twitter) and LinkedIn.

Media Contact

Media@Recursion.com

Investor Contact

Investor@Recursion.com

Forward-Looking Statements

This document contains information that includes or is based upon “forward-looking statements” within the meaning of the Securities Litigation Reform Act of 1995, including, without limitation, those regarding the clinical relevance of the SYCAMORE trial data and obtaining additional confirmatory data; promising trends in REC-994 efficacy endpoints; Recursion’s plans to submit SYCAMORE trial data for publication in a peer-reviewed journal; advancing potential transformational therapies for CCM and beyond; subsequent REC-994 studies and their results and advancing Recursion’s REC-994 program further; the size of the potential CCM patient population; Recursion OS and other technologies; business and financial plans and performance; and all other statements that are not historical facts. Forward-looking statements may or may not include identifying words such as “plan,” “will,” “expect,” “anticipate,” “intend,” “believe,” “potential,” “continue,” and similar terms. These statements are subject to known or unknown risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements, including but not limited to: challenges inherent in pharmaceutical research and development, including the timing and results of preclinical and clinical programs, where the risk of failure is high and failure can occur at any stage prior to or after regulatory approval due to lack of sufficient efficacy, safety considerations, or other factors; our ability to leverage and enhance our drug discovery platform; our ability to obtain financing for development activities and other corporate purposes; the success of our collaboration activities; our ability to obtain regulatory approval of, and ultimately commercialize, drug candidates; our ability to obtain, maintain, and enforce intellectual property protections; cyberattacks or other disruptions to our technology systems; our ability to attract, motivate, and retain key employees and manage our growth; inflation and other macroeconomic issues; and other risks and uncertainties such as those described under the heading “Risk Factors” in our filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. All forward-looking statements are based on management’s current estimates, projections, and assumptions, and Recursion undertakes no obligation to correct or update any such statements, whether as a result of new information, future developments, or otherwise, except to the extent required by applicable law.

Photos accompanying this announcement are available at:

<https://www.globenewswire.com/NewsRoom/AttachmentNg/d81f369a-3622-4ffc-b298-a2a3a31047a0>

<https://www.globenewswire.com/NewsRoom/AttachmentNg/b4285139-1d7e-42e3-95d8-a12bc8ea58a8>

<https://www.globenewswire.com/NewsRoom/AttachmentNg/8090c106-c7e6-416f-9060-c16ee5bb53ee>



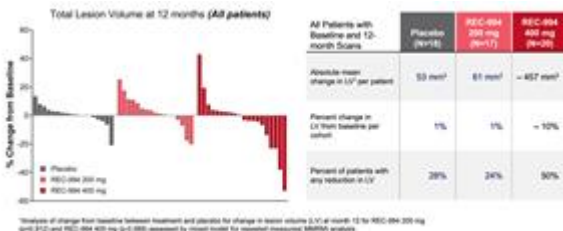
Ph2 Data

| Event, n (%) | Placebo (n=18) | REC-994 200 mg (n=21) | REC-994 400 mg (n=21) | Total (n=60) |
|---|----------------|-----------------------|-----------------------|--------------|
| Any Treatment Emergent Adverse Event (TEAE) | 17 (94.4) | 18 (85.7) | 19 (91.4) | 54 (90.6) |
| TEAEs Grade ≥3 | 4 (22.2) | 7 (33.3) | 3 (14.3) | 14 (23.3) |
| Any TEAE related to study drug ¹ | 2 (11.1) | 0 | 5 (23.8) | 7 (11.7) |
| Grade ≥3 TEAE | 0 | 0 | 0 | 0 |
| Discontinuation due to TEAE | 0 | 0 | 0 | 0 |
| Dose interruption due to TEAE | 0 | 0 | 0 | 0 |

¹In the REC-400 mg arm these consisted of dizziness, rash, anemia, nausea and peripheral edema. In the placebo arm these consisted of dizziness and erythema multiforme. Across both arms, TEAEs related to study drug were Grade 1 or 2.

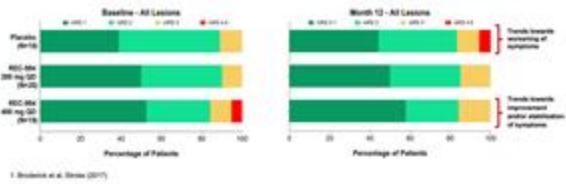
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Total Lesion Volume (12 Months)



1. Analysis of change from baseline between treatment and placebo for change in lesion volume (LV) at month 12 for REC-994 200 mg (p=0.987) and REC-994 400 mg (p=0.449) assessed by mixed model for repeated measures (MMRM) analysis

Baseline All Lesions



Exploratory Analysis: Modified Rankin Scale (mRS) Suggests REC-994 Improved Clinical Function in CCM Patients

Source: Recursion Pharmaceuticals, Inc.