Reviva Pharmaceuticals Announces Update on RECOVER, a Pivotal Phase 3 Global Study Evaluating Brilaroxazine for the Treatment of Schizophrenia

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CUPERTINO, Calif., May 03, 2022 (GLOBE NEWSWIRE) -- Reviva Pharmaceuticals Holdings, Inc. (NASDAQ: RVPH) ("Reviva" or the "Company"), a clinical-stage pharmaceutical company developing therapies that seek to address unmet medical needs in the areas of central nervous system (CNS), cardiovascular, metabolic, and inflammatory diseases, today announced that the RECOVER study is progressing well and all sites in the United States (U.S.) have been initiated. Global sites in Europe and India remain on track to initiate in mid-2022.

"We are extremely fortunate to have a team of industry experts with decades of clinical trial experience working in concert with our external CRO to ensure timelines remain on track for both the main 28 day once daily dose double-blind study in patients with acute schizophrenia as well as the 52-week open label extension study to further evaluate the long-term safety and tolerability of brilaroxazine in patients with stable schizophrenia," said Laxminarayan Bhat, Ph.D., Founder, President, and CEO. "The Phase 3 RECOVER study continues to progress well, with brilaroxazine demonstrating a safe and well tolerated profile with no serious treatment related events to date. We look forward to sharing further updates on enrollment in the second half of 2022 and anticipate providing topline data in mid-2023."

RECOVER is a global Phase 3, randomized, double-blind, placebo-controlled, multicenter study designed to assess the safety and efficacy of brilaroxazine in approximately 400 patients with acute schizophrenia compared to placebo. Brilaroxazine will be administered at fixed doses of 15 mg or 50 mg once daily for 28 days. A 52-week open-label extension study will further evaluate the long-term safety and tolerability of brilaroxazine in patients with stable schizophrenia. Since Reviva initiated its first clinical site in Bentonville, Arkansas, led by principal investigator Dr. Fayz A. Hudefi, M.D. at the end of January, the team has initiated 15 geographically diverse sites across the United States. The ex-US sites in Europe and India remain on track to initiate in mid-2022.

About Reviva
Reviva is a clinical-stage biopharmaceutical company that discovers, develops and seeks to commercialize next-generation therapeutics for diseases representing unmet medical needs and burdens to society, patients, and their families. Reviva's current pipeline focuses on the central nervous system, respiratory and metabolic diseases. Reviva's pipeline currently includes two drug candidates, RP5063 (brilaroxazine) and RP1208. Both are new chemical entities discovered in-house. Reviva has been granted composition of matter patents for both RP5063 and R1208 in the United States (U.S.), Europe, and several other countries.

Forward-Looking Statements
This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act, as amended, including those relating to the Company's RECOVER trial, product development, clinical and regulatory timelines and expenses, market opportunity, ability to raise sufficient funding, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statements that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions. These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Corporate Contact:
Reviva Pharmaceuticals Holdings, Inc.
Laxminarayan Bhat, PhD
www.revivapharma.com

Investor Relations Contact:
LifeSci Advisors, LLC
Bruce Mackle
bmackle@lifesciadvisors.com

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