Reviva Announces Enrollment Update for Open Label Extension Study Evaluating Brilaroxazine in Schizophrenia

- 108 patients have completed 1-year of treatment -

- Brilaroxazine is generally well tolerated to date in patients with acute and stable schizophrenia -

- Topline data from 1-year open-label extension (OLE) trial now expected in December 2024 -

CUPERTINO, Calif., Nov. 12, 2024 (GLOBE NEWSWIRE) -- Reviva Pharmaceuticals Holdings, Inc. (NASDAQ: RVPH) ("Reviva" or the "Company"), a late-stage pharmaceutical company developing therapies that seek to address unmet medical needs in the areas of central nervous system (CNS), inflammatory and cardiometabolic diseases, today announced an enrollment update to the ongoing 1-year open-label extension (OLE) study evaluating the long-term safety and tolerability of brilaroxazine in patients with schizophrenia.

"We are pleased with the pace of enrollment of our OLE study which includes 108 patients that have completed 12 months of treatment and over 250 patients have completed 6 months of treatment. Importantly, we have collected long-term safety data in 100 patients with one year of treatment which is a requirement for our planned New Drug Application (NDA) submission to the Food and Drug Administration (FDA)," said Laxminarayan Bhat, Ph.D., Founder, President, and CEO of Reviva. "Brilaroxazine continues to be generally well tolerated across patients with acute and stable schizophrenia in the OLE study to date. We now expect to report topline 12-month long-term safety and efficacy data in December of 2024."

RECOVER Trial OLE Enrollment Status Update as of November 12, 2024

- Global trial progressing well
- 108 patients have completed 1-year (12-month) of treatment
- Over 250 patients have completed 6-months of treatment
- Blood and digital biomarkers designed to independently support efficacy
- Long-term safety data from 100 patients who have completed 12 months of treatment is a requirement for brilaroxazine's NDA submission to the FDA
- 12 months long-term safety study to complete in Q1 2025

The RECOVER Trial OLE is a randomized, double-blind, placebo-controlled, multicenter study to assess the efficacy and safety of brilaroxazine at fixed doses of 15 mg or 50 mg, administered once daily for 28 days in subjects with an acute exacerbation of schizophrenia, followed by the long-term safety assessment of brilaroxazine at flexible doses of either 15, 30 or 50 mg administered once daily for 52 weeks in subjects with stable schizophrenia. The OLE study will include both double-blind rollover and de novo subjects with stable schizophrenia.

About Brilaroxazine
Brilaroxazine is an in-house discovered new chemical entity with potent affinity and selectivity against key serotonin and dopamine receptors implicated in the pathophysiology of several conditions including schizophrenia, psoriasis and interstitial lung diseases like pulmonary hypertension, pulmonary arterial hypertension (PAH) and idiopathic pulmonary fibrosis (IPF).

Positive topline data from the global Phase 3 RECOVER trial in schizophrenia demonstrated the trial successfully met all primary and secondary endpoints with statistically significant and clinically meaningful reductions across all major symptom domains including reduction in key proinflammatory cytokines implicated in the pathophysiology of schizophrenia and comorbid inflammatory conditions at week 4 with 50 mg of brilaroxazine vs. placebo, with a generally well-tolerated side effect profile comparable to placebo and discontinuation rates *lower* than placebo. Positive data from a clinical drug-drug interaction (DDI) study investigating the potential effect of the CYP3A4 enzyme on brilaroxazine in

healthy subjects supports no clinically significant interaction when combined with a CYP3A4 inhibitors. Reviva believes that a full battery of regulatory compliant toxicology and safety pharmacology studies has been completed for brilaroxazine. Reviva intends to develop brilaroxazine for other neuropsychiatric indications including bipolar disorder, major depressive disorder (MDD) and attention-deficit/hyperactivity disorder (ADHD).

Additionally, brilaroxazine has shown promising nonclinical activity for inflammatory diseases psoriasis, pulmonary arterial hypertension (PAH) and idiopathic pulmonary fibrosis (IPF) with mitigation of fibrosis and inflammation in translational animal models. Brilaroxazine has already received Orphan Drug Designation by the U.S. FDA for the treatment of PAH and IPF conditions. To learn more about the clinical and preclinical data available for brilaroxazine, please visit revivapharma.com/publications.

About Reviva

Reviva is a late-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 (CNS), inflammatory and cardiometabolic diseases. Reviva's pipeline currently includes two drug candidates, brilaroxazine (RP5063) and RP1208. Both are new chemical entities discovered in-house. Reviva has been granted composition of matter patents for both brilaroxazine and RP1208 in the United States, 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 1-year open label extension (OLE) trial evaluating the long-term safety and tolerability for brilaroxazine in schizophrenia, the registrational Phase 3 RECOVER-2 trial, the Company's expectations regarding the anticipated clinical profile of its product candidates, including statements regarding anticipated efficacy or safety profile, and those relating to the Company's expectations, intentions or beliefs regarding matters including product development, clinical and regulatory timelines and expenses, planned or additional studies, planned or intended regulatory submissions, market opportunity, ability to raise sufficient funding, competitive position, possible or assumed future results of operations, business strategies, potential opportunities for development including partnerships, growth or expansion 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 most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2023, and the Company's other filings from time to time 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

11/12/2024 8:00:00 AM