Reviva Announces New Vocal Biomarker Data from Phase 3 RECOVER Trial of Brilaroxazine in Schizophrenia

– Statistically significant vocal biomarker speech latency data reinforce the strong efficacy of brilaroxazine for negative symptoms and other key symptom domains of schizophrenia –

– Additional vocal biomarker data from ongoing open label extension study evaluating brilaroxazine in schizophrenia expected Q4 2024 –

CUPERTINO, Calif., Sept. 09, 2024 — 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 announces new vocal biomarker data from Phase 3 RECOVER trial of brilaroxazine in schizophrenia was presented during a virtual key opinion leader event hosted by the Company on September 4, 2024 featuring Brian Kirkpatrick, MD, MSPH (Professor, Psychiatric Research Institute, University of Arkansas for Medical Sciences, Arkansas) and Mark Opler, PhD, MPH (Chief Research Officer at WCG Inc., Executive Director of the PANSS Institute, New York). A replay of the event can be found at https://revivapharma.com/events/.

"Brilaroxazine has demonstrated a safety profile comparable to placebo, with broad spectrum efficacy across the major symptom domains of schizophrenia, including negative symptoms," said Laxminarayan Bhat, Ph.D., Founder, President, and CEO of Reviva. "These new vocal biomarker data provide an objective tool that further supports the primary and secondary endpoints evaluated in the RECOVER trial. We look forward to further evaluating vocal biomarker data from patients in our ongoing open label extension study with topline data expected in the fourth quarter of the year."

Dr. Brian Kirkpatrick, Professor, Psychiatric Research Institute, University of Arkansas for Medical Sciences added, "The results using this objective, automated vocal biomarker confirms robust treatment effects on total, positive, and negative symptoms, social function, disorganization and overall efficacy following treatment with brilaroxazine. These findings are consistent with previous assessments and add to the clinical data supporting a strong treatment effect across domains with brilaroxazine."

Key highlights of the vocal biomarker data include:

- Speech latency is an emerging objective vocal biomarker that can help validate scale-based assessments completed by human raters
- Brilaroxazine demonstrated a strong efficacy for negative symptoms and other key symptoms of schizophrenia such as total and positive symptoms, disorganization, and

social functioning in the pivotal phase 3 RECOVER trial in schizophrenia

- Statistically significant results of the vocal biomarker speech latency data analysis from the RECOVER trial further support the strong efficacy of brilaroxazine for negative symptoms and other key symptom domains of schizophrenia

Dr. Mark Opler, Chief Research Officer at WCG Inc. and Executive Director of the PANSS Institute, New York added, “Current marketed therapies do not address critical aspects of schizophrenia such as negative symptoms and cognition. In addition to suboptimal efficacy, the poor tolerability of current antipsychotics also contributes to low treatment adherence and high discontinuation rates across patients. The consistent, widespread efficacy of brilaroxazine across multiple domains, coupled with the very strong efficacy-to-side-effect ratio, supports the potential of brilaroxazine to significantly address unmet needs in the treatment of 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 and clinical trial plans, clinical and regulatory timelines and expenses, planned or intended additional trials or studies and the timing thereof, planned or intended regulatory submissions and the timing thereof, trial results, 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.

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