Reviva Announces Positive Full Dataset for 1-Year Phase 3 RECOVER Open Label Extension Study Evaluating Brilaroxazine in Schizophrenia

– Robust broad-spectrum efficacy sustained over 1-year across all symptom domains including negative symptoms –

– Generally well-tolerated with low rates of adverse events and discontinuation –

– Brilaroxazine improved multiple neuroinflammatory markers reported to enhance efficacy and mitigate side effects –

– Virtual investor webcast today at 8:00 a.m. EDT –

CUPERTINO, Calif., June 02, 2025 (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 a positive full dataset and successful completion of the Company's Phase 3 RECOVER open-label extension (OLE) 1-year study evaluating the long-term safety, tolerability and efficacy of brilaroxazine in patients with schizophrenia. Once daily brilaroxazine led to robust broad-spectrum efficacy that was sustained over 1-year and was generally well tolerated with a discontinuation rate of 35% in this long-term study. Brilaroxazine is a novel serotonin dopamine signaling modulator with multi-faceted direct and indirect activities on critical pathways implicated in schizophrenia. To register for the virtual investor webcast being held today, June 2, 2025 at 8:00 a.m. EDT regarding the OLE trial data, please visit https://lifescievents.com/event/h4p8mx9cj0w/.

"We are pleased to complete the positive registrational trial for our brilaroxazine program in schizophrenia and generate long-term data reinforcing brilaroxazine's consistent, wide-spectrum efficacy, and well-tolerated safety profile," said Laxminarayan Bhat, Ph.D., Founder, President, and CEO of Reviva. "Importantly, the additional multiple biomarker data serve as independent measures of efficacy that further support improvements across all major symptom domains of schizophrenia. Our clinical program continues to advance towards registration, and we look forward to bringing brilaroxazine to more patients globally as fast as possible."

Dr. Stephen R Marder, MD, Professor, Psychiatry and Biobehavioral Sciences at the University of California, Los Angeles added, "Dissatisfaction with current standards of care is largely driven by persistent negative symptoms and poor functional outcomes. The robust improvement in negative symptoms and sustained broad-spectrum efficacy support the potential of brilaroxazine to address these unmet needs."

Dr. Larry Ereshefsky, PharmD, BCPP, FCCP, Retired Professor of Psychiatry, Pharmacology and

Psychiatry, The University of Texas added, “Brilaroxazine improved multiple biomarkers including reduced levels of inflammatory cytokines that could contribute to enhanced efficacy and mitigate side effects. The impact of reduced inflammation on symptoms may result in improved patient adherence and clinical outcomes. The low discontinuation rates observed in the double-blind and OLE trials are consistent with this beneficial treatment profile.”

Key safety, efficacy and compliance findings for pooled analysis of brilaroxazine (n = 446) at 15 mg (n = 140), 30 mg (n = 158), and 50 mg (n = 148) include: Dose-dependent, broad spectrum, clinically meaningful and sustained long-term (1-year) efficacy across all major symptom domains of schizophrenia.

Point Improvement from Baseline to End of Treatment for Brilaroxazine Pooled (15, 30, and 50 mg) at 6-month and 12-month, *p* 0.001

	OLE at 6-month (N=303)	OLE at 12-month (N=159)	Rollover Patients, Double-blind to OLE at 13-month (N=50)
PANSS Total Score	-10.7	-18.1	-47.7
Positive Symptoms	-3.3	-5.0	-14.0
Negative Symptoms	-2.8	-4.4	-10.5
Negative Marder Factor	-3.0	-4.4	—
PANSS Social Cognition	-1.5	-2.9	—
Personal and Social Performance	4.5	11.3	32.7
CGI-S score >1-point	37.3%	58.5%	100%
PANSS Excitement/Agitation	-1.4	-3.5	—
PANSS General Psychopathology	-4.7	-8.7	23.2

PANSS: Positive and Negative Syndrome Scale; CGI-S: Clinical Global Impression – Severity

Clinical safety, tolerability and adherence findings with pooled doses of brilaroxazine (15, 30, and 50 mg) in the OLE trial patients (N=446) support a well-tolerated safety profile:

- 8.5% of participants reported at least one treatment-emergent adverse event (TEAE), which were mostly mild (6.5%) or moderate (2.0%) in severity and transient in nature
- Most common TEAEs 2% were headache (2.7%), insomnia (4.0%), sleep disturbance (2.9%) and mild tremor (3.1%)
- Brilaroxazine was not associated with any clinically meaningful changes in movement disorder scales used for evaluating motor side effects such as akathisia and extrapyramidal symptoms over 1-year treatment
- Mild weight gain (1.52 kg) reported in the pooled brilaroxazine dose group over 1-year treatment. Weight gain was not dose dependent with least weight gain (1.28 kg) at 50 mg dose

- No drug related serious adverse events (SAEs) observed or major safety concerns reported for brilaroxazine after 1-year of treatment; 5 serious adverse events were reported, and none were related to brilaroxazine treatment
- No incidence of clinically significant cardiac side effects, or gastrointestinal side effects
- No incidence of drug induced liver injury (DILI)
- No significant change in blood glucose levels
- Improved lipids levels and endocrine hormone levels (prolactin, and thyroid)
- Treatment discontinuation rate of 35% reported in this one-year study primarily due to withdrawal of consent (22%), participant lost to follow up (7%) and treatment related adverse events (1.1%)

We believe that collectively, the Phase 3 RECOVER OLE study (52-week/1-year) findings further strengthen the safety, efficacy and treatment adherence findings in the Phase 3 RECOVER double-blind study (4-week).

The RECOVER OLE Study is a global, open-label, multicenter study to assess the safety, tolerability and efficacy of brilaroxazine at flexible doses of 15, 30 or 50 mg, administered once daily for 52-week (1-year) in patients with stable schizophrenia. The OLE study included both rollover participants from the RECOVER double-blind study and de novo participants with stable schizophrenia. Long-term safety data from 100 patients who have completed 1-year of treatment is a requirement for brilaroxazine's NDA submission to the U.S. Food and Drug Administration ("FDA").

Webcast Information

To register for the virtual investor webcast being held today, June 2, 2025 at 8:00 a.m. EDT regarding the OLE trial data, please visit https://lifescievents.com/event/h4p8mx9cj0w/. Subsequent to today's live webcast, a replay will be made available on Reviva's website at https://revivapharma.com/events. The archived version of the webcast will be available on the Company's website for at least 30 days.

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 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 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, the timing of availability of additional data or initiation of additional trials, 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, 2024, 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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