Reviva Announces Publication on Clinical Vocal Biomarker Data from the RECOVER Phase 3 Clinical Trial of Brilaroxazine to Treat Negative Symptoms in Schizophrenia

Findings reinforce brilaroxazine's treatment effect on negative symptoms and other symptom domains in schizophrenia and support clinician-assessed efficacy outcomes in a Phase 3 trial of brilaroxazine

Findings also support use of speech latency as an enrichment tool that can reduce sample-size and enhance outcomes in clinical trials for schizophrenia

CUPERTINO, Calif., Jan. 08, 2026 (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 the publication, in the peer-reviewed journal *Biological Psychiatry*, of an article entitled A Single, Interpretable Vocal Biomarker for Enriching Antipsychotic Clinical Trials that highlights clinical vocal biomarker data from the RECOVER Phase 3 clinical trial and the therapeutic potential of brilaroxazine for the treatment of schizophrenia. The publication is available at revivapharma.com/publications.

"Publication of our vocal biomarker findings from our RECOVER Phase 3 trial in this top-tier, peer-reviewed journal underscores the robustness of our clinical data and the differentiated therapeutic potential of brilaroxazine to address unmet needs in schizophrenia and its major symptom domain negative symptoms," said Laxminarayan Bhat, Ph.D., Founder, President, and CEO of Reviva. "These results show speech latency as a scalable, objective biomarker that can be used to evaluate brilaroxazine's effect on negative symptoms and other core domains of schizophrenia, as well as corroborative of clinician-assessed efficacy from our trial. Beyond this program, we believe this approach could transform limitations of current schizophrenia clinical trials by improving patient stratification, enriching for primary negative symptom populations, and mitigating placebo responses, all of which are factors critical to trial success rates."

Highlights of brilaroxazine vocal or speech biomarker data from the pivotal Phase 3 RECOVER trial in schizophrenia include:

- Speech latencies classified the presence of moderate to severe negative symptoms (VBM-positive) and low negative symptoms (VBM-negative) in patients randomized to the RECOVER trial.
- A greater percentage of VBM positive patients showed significant treatment response, as measured by clinician assessed efficacy outcomes of brilaroxazine for negative symptoms and other key symptom domains of schizophrenia.

- VBM-positive patients showed a fast and strong response to brilaroxazine treatment in nearly every outcome measure, especially negative symptoms.

Speech latency, an objective measure of verbal response time, is sensitive to cognitive, social, and motivational factors, and can be assayed from psychiatric interviews. Speech latency differentiates patients with moderate-to-severe vs. low negative symptoms across countries and languages. As an enrichment tool, it could reduce sample-size needs and enhance the trial outcomes thereby reducing clinical trial costs and burden.

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 a potential second Phase 3 clinical trial for brilaroxazine in patients with schizophrenia, anticipated efficacy or safety profile, statements about biomarker data and its utility including in terms of reinforcing treatment effect, supporting clinician-assessed efficacy outcomes, and reducing sample-size and enhancing outcomes in clinical trials, 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 potential additional trials and the timing thereof, planned or intended regulatory submissions and the timing thereof, the timing of availability of additional data or initiation of additional trials, trial results, market opportunity, costs of additional trials including statements about estimated costs, and the risk that the actual cost of trials and the Company's actual expenses may be higher than the Company projects in its estimates, ability to raise sufficient funding, including in an amount sufficient to support the Company's intended additional trials, trial results, statements about expected approvals or the timing at which approval might be anticipated, market opportunity, 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, on the Company's operations, clinical development and clinical trial plans, timelines and estimates, 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, the Company's Quarterly Reports on Form 10-Q filed since such most recent Annual Report on Form 10-K, 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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