Reviva Announces Regulatory Update Regarding the Development of Brilaroxazine for the Treatment of Schizophrenia

Written feedback from FDA pre-NDA meeting includes a recommendation to conduct a second Phase 3 trial to generate additional efficacy and safety data prior to NDA submission of brilaroxazine for the treatment of schizophrenia

Current data package highlights long-term safety profile, broad-spectrum clinical activity, and favorable adherence observed to date for once daily brilaroxazine over up to one year

Initiation of RECOVER-2 registrational trial planned in H1 2026, subject to sufficient financing

CUPERTINO, Calif., Dec. 23, 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 regulatory update following a pre-New Drug Application (pre-NDA) meeting with the U.S. Food and Drug Administration (FDA) regarding brilaroxazine, a novel serotonin-dopamine and neuroinflammatory signaling modulator, in late-stage development for the treatment of schizophrenia.

In written feedback, the FDA recommended a second Phase 3 clinical trial for brilaroxazine in patients with schizophrenia to, among other things, generate additional efficacy data and expand the safety dataset. Subject to sufficient financing, Reviva plans to initiate the RECOVER-2 Phase 3 trial in the first half of 2026. The RECOVER-2 trial will be similar in design to the completed RECOVER Phase 3 trial of brilaroxazine. The FDA also provided the Company with guidance for, among other topics, methods of data analysis, methods of data presentation, and data requirements for studies of animal pharmacokinetics, human abuse potential, and renal and hepatic impairment.

"We appreciate the clear and constructive feedback from the FDA. Across our robust clinical data package, brilaroxazine continues to show potential to address unmet needs in schizophrenia, with data reflecting broad-spectrum efficacy, a well-characterized and generally favorable safety profile, and favorable treatment adherence observed to date, with convenient once-daily oral administration," said Laxminarayan Bhat, Ph.D., Founder, President, and CEO of Reviva. "We are committed to working closely with the FDA to generate the additional efficacy and safety data necessary to support a potential NDA and to potentially bring brilaroxazine to patients with schizophrenia as quickly as possible. Subject to sufficient financing, we plan to initiate RECOVER-2 in the first half of 2026."

The recommendation follows FDA review of the Company's existing nonclinical and clinical data package, including two completed randomized, double-blind, placebo-controlled,

multicenter clinical trials (one Phase 2 trial and one Phase 3 trial that included a 1-year open label extension) and clinical pharmacology studies designed to support a potential NDA filing. Across the clinical development program, brilaroxazine has demonstrated the following:

- Broad spectrum efficacy in major symptom domains of schizophrenia, including negative symptoms, in the 790 subjects that participated in the Phase 2 and Phase 3 (double-blind and open-label portions) clinical trials
- A generally well-tolerated safety profile, observed in the over 900 subjects treated to date

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, 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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