Reviva Announces Enrollment Completion for Pivotal Phase 3 RECOVER Study for Brilaroxazine in Schizophrenia

– 402 patients completed enrollment across multiple sites in the US, Europe, and Asia –

– Topline data for Phase 3 RECOVER study expected in October 2023 –

– Completion of 1-year open-label extension clinical study expected in Q3 2024 –

CUPERTINO, Calif., Aug. 17, 2023 — 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 that enrollment is complete in the pivotal Phase 3 RECOVER study evaluating brilaroxazine for schizophrenia, with 402 patients enrolled at multiple sites in the United States (~60%), Europe (~10%), and Asia (~30%).

"Completing enrollment of all 402 patients across 40 global sites in the pivotal Phase 3 RECOVER trial is a key milestone for our late-stage program in schizophrenia," said Laxminarayan Bhat, Ph.D., Founder, President, and CEO of Reviva. "We believe RECOVER will further reinforce the ability of brilaroxazine to improve multiple symptom domains of schizophrenia including positive and negative symptoms and neuroinflammation and demonstrate a well-tolerated safety profile with no cardiac or metabolic side effects as seen in our Phase 2 trial. We are also pleased to announce that we have over 50% of patients enrolled in our 1-year open-label extension study for brilaroxazine in schizophrenia. We look forward to reporting topline efficacy and safety data from RECOVER expected in October 2023."

RECOVER is a global Phase 3, randomized, double-blind, placebo-controlled, multicenter study designed to assess the safety and efficacy of brilaroxazine in 402 patients with acute schizophrenia compared to placebo. Brilaroxazine will be administered at fixed doses of 15 mg or 50 mg once daily for 28 days. The primary endpoint is a decrease in Positive and Negative Symptoms Assessment total score compared to placebo from baseline to Day 28. Key secondary endpoints include clinical global impression (CGI) rating scale, positive and negative symptoms, social functioning and cognition. A 1-year open-label extension (OLE) study with flexible doses of 15 mg, 30 mg, or 50 mg will further evaluate the long-term safety and tolerability of brilaroxazine in patients with stable schizophrenia. Over 50% of patients are currently enrolled in the OLE, with completion of the required 100 patients treated with brilaroxazine for 1-year expected in Q3 2024.

About Brilaroxazine

Brilaroxazine is an in-house discovered new chemical entity with potent affinity and

selectivity against key serotonin and dopamine receptors implicated in schizophrenia and its comorbid symptoms. In a multinational, multicenter, double-blind Phase 2 study in 234 patients with acute schizophrenia or schizoaffective disorder, brilaroxazine met its primary endpoint, reducing Positive and Negative Syndrome Scale (PANSS) total score and demonstrating statistically significant improvement of overall drug treatment outcomes using Clinical Global Impression (CGI) scale and for secondary endpoints evaluating social functioning, and positive and negative symptoms, and directional improvements for depression and cognition. In this completed Phase 2 study, brilaroxazine met all safety endpoints with no weight gain, no increase in blood sugar and lipids, and no cardiac or endocrine adverse effects compared to placebo. Positive data from a clinical drug-drug interaction (DDI) study investigating the potential effect of CYP3A4 enzyme on brilaroxazine in healthy subjects supports no clinically significant interaction when combined with a CYP3A4 inhibitor. A full battery of regulatory compliant toxicology and safety pharmacology studies has been completed for brilaroxazine. The U.S. Food and Drug Administration (FDA) has agreed to consider a potential superior safety label claim if there is a positive outcome on a relevant endpoint in a pivotal Phase 3 study in patients with schizophrenia. 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 efficacy 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 pharmaceutical 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, inflammatory and cardiometabolic diseases. Reviva’s pipeline currently includes two drug candidates, RP5063 (brilaroxazine) and RP1208. Both are new chemical entities discovered in-house. Reviva has been granted composition of matter patents for both RP5063 and RP1208 in the United States (U.S.), 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 Phase 3 RECOVER study and timing of topline data, the Company's open-label extension clinical trial for brilaroxazine in schizophrenia, 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 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, 2022, 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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