Reviva Announces FDA Alignment on Brilaroxazine Clinical Trials for NDA in Schizophrenia

– FDA acceptance of 4-week global registrational Phase 3 RECOVER-2 study –

– Two positive 4-week studies plus a 12-month long-term safety study have potential to support a New Drug Application (NDA) for brilaroxazine in schizophrenia –

– Topline data from 1-year open-label extension (OLE) long-term safety trial expected in Q4 2024 –

CUPERTINO, Calif., April 15, 2024 — Reviva Pharmaceuticals Holdings, Inc. (NASDAQ: RVPH), 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, announced today it has gained alignment with the U.S. Food and Drug Administration (FDA) on its registrational Phase 3 program for brilaroxazine in schizophrenia.

The FDA accepted a 4-week RECOVER-2 study for brilaroxazine in schizophrenia. Notably, the FDA also indicated that two positive Phase 3 studies showing efficacy at week 4 that are accompanied by long-term safety data of at least 12 months could be supportive of an NDA submission for the acute treatment of schizophrenia. In addition, FDA indicated that it will require a long-term randomized withdrawal study post-approval to support maintenance of effect.

“We are pleased to receive positive feedback from the FDA and acceptance of a 4-week registrational study for our brilaroxazine program,” said Laxminarayan Bhat, Ph.D., Founder, President, and CEO of Reviva. “The FDA also clarified that our NDA submission could include two 4-week phase 3 studies showing efficacy and a 12-month long-term safety study. Importantly, we have already successfully completed and announced the results of our pivotal Phase 3 RECOVER trial in October 2023, and we are set to initiate our RECOVER-2 trial during this quarter. We expect topline data from our 1-year OLE trial in the fourth quarter of this year. Collectively, we expect to have completed all of the outlined NDA submission requirements by the third quarter of 2025.”

RECOVER-2 is a global Phase 3, randomized, double-blind, placebo-controlled, multicenter, 4-week study designed to assess the safety and efficacy of brilaroxazine in approximately 450 patients with acute schizophrenia compared to placebo. Brilaroxazine will be administered at fixed doses of 30 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) severity, positive and negative symptoms, social functioning, and cognition, and key biomarkers implicated in

neuroinflammation. Reviva plans to initiate the first clinical site in this quarter (Q2-2024).

About Schizophrenia

Schizophrenia is a complex and debilitating neuropsychiatric disorder that affects ~1% of the world's population, and approximately 3.5 million people in the United States alone and 20 million globally. Characterized by multiple symptoms, patients with schizophrenia often suffer from cognitive impairment, delusions, hallucinations and disorganized speech or behavior. Despite its high prevalence, there are no therapies that adequately address the complex mix of positive and negative symptoms, mood, and cognitive impairment associated with schizophrenia. Limitations of current treatments include suboptimal efficacy, poor tolerability, and low patient adherence rates.

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. Positive topline data from the global Phase 3 RECOVER-1 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 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 CYP3A4 enzyme on brilaroxazine in healthy subjects supports no clinically significant interaction when combined with a CYP3A4 inhibitor. 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, 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 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, 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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