# Reviva Announces Grant of European Patent Covering Use of Brilaroxazine for the Treatment of Pulmonary Hypertension

- Patent covers brilaroxazine use for treating pulmonary hypertension (PH), pulmonary arterial hypertension (PAH) in any patients including treating PH in patients with chronic obstructive pulmonary disease (COPD) or sickle cell disease (SCD)

-Similar patents have also been granted in key markets around the world including the United
States, China, and Japan

-Brilaroxazine has a novel mechanism of action for treating the underlying disruption in serotonin signaling implicated in the pathogenesis of PH/PAH

CUPERTINO, Calif., July 09, 2024 — 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 European Patent EP3244896 has been granted by the European Patent Office (EPO) covering use of brilaroxazine for the treatment of PH, adding to its existing patent protection in key markets around the world including the United States, China and Japan. The European patent covers brilaroxazine use for treating PH and PAH in any patients and treating PH in patients with COPD or SCD. Brilaroxazine has received Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the treatment of PAH.

"This latest patent further secures the broad therapeutic potential of brilaroxazine for inflammatory conditions driven by underlying disruption in serotonin signaling like pulmonary hypertension," said Laxminarayan Bhat, Ph.D., Founder, President, and CEO. "Brilaroxazine has demonstrated a favorable clinical safety and tolerability profile in over 800 subjects to date from multiple clinical trials. A significant reduction in key proinflammatory biomarkers following brilaroxazine treatment was recently shown in a large, global, pivotal Phase 3 study in patients with schizophrenia. Building on this promising clinical data, potent anti-inflammatory and antifibrotic activities and significant reduction in pulmonary arterial pressure has been shown in translational animal models for PAH following brilaroxazine treatment, and we look forward to further evaluating brilaroxazine's unique multi-modal mechanism of action with clinical development expansion opportunities in PH and PAH."

### **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 pathobiology 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-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 including reduction in key proinflammatory cytokines implicated in the pathobiology 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 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 potential additional indications for the Company's product candidates, 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 for the fiscal year ended December 31, 2023, 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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