Reviva Pharmaceuticals Announces Letter to Shareholders

CUPERTINO, Calif., Jan. 04, 2023 — Reviva Pharmaceuticals Holdings, Inc. (NASDAQ: RVPH) ("Reviva" or the "Company"), a clinical-stage pharmaceutical company developing therapies that seek to address unmet medical needs in the areas of central nervous system (CNS), cardiovascular, metabolic, and inflammatory diseases, is pleased to announce a letter to shareholders from Founder, President, and CEO, Laxminarayan Bhat, Ph.D.

The full text of the letter follows.

Dear Fellow Shareholders:

It is with great pride and enthusiasm that I write this shareholder letter to you today.

Despite COVID-19 and shifting geopolitical landscape resulting in widespread delays that have impacted a large number of clinical trials in recent years, Reviva Pharmaceuticals remains on track to report top-line data in mid-2023 from our global, pivotal Phase 3 RECOVER trial of brilaroxazine in schizophrenia patients. We made significant progress on this program in 2022, finishing the year with about 40% of patients treated and no treatment-related serious adverse events reported, further demonstrating the strong safety profile of this novel investigational treatment that we hope can ultimately improve the quality of life for patients globally. We believe that with this progress, bolstered by our improved financial position and responsible management of resources, we are at a strong competitive position.

Strengthened Financial Position

The successful closing of a registered direct offering and concurrent private placement in September 2022, which raised gross proceeds of $8.5 million, provided financial support for the completion of our pivotal Phase 3 trial in schizophrenia. This capital raise, led by a current institutional investor of Reviva, is an important milestone that we believe demonstrates a strong belief in our ability to deliver results. The financing also included investments from two affiliates of one of our board members, serving as an additional affirmation of confidence in the potential of our development pipeline.

Top-Line Data from Phase 3 Trial is Expected in Mid-2023

We have made significant progress since initiating the first clinical site for our pivotal Phase 3 RECOVER trial of brilaroxazine in the US in late January of 2022 and remain on pace to report top-line data in mid-2023 with patient enrollment ongoing at geographically diverse sites. Brilaroxazine is a serotonin/dopamine modulator in late-stage clinical development for the treatment of schizophrenia.

The RECOVER trial is a global Phase 3, randomized, double-blind, placebo-controlled, multicenter study designed to assess the safety and efficacy of brilaroxazine in approximately 400 patients with acute schizophrenia compared to placebo. Currently, we

have treated about 40% of patients in this program, and importantly, have done so with no treatment-related serious adverse events reported. We remain highly encouraged by the potential of brilaroxazine to offer a safe, well-tolerated and efficacious treatment option for patients with schizophrenia, which afflicts an estimated 24 million people worldwide.

In December, we announced the completion of an important clinical drug-drug interaction (DDI) study investigating the potential effect of CYP3A4 enzyme on brilaroxazine in healthy subjects. The CYP3A4 enzyme plays a vital role in helping the body metabolize and remove small foreign molecules and is primarily found in the liver and intestine. Approximately 50% of prescribed drugs and over 25% of antipsychotics currently on the market are known to cause drug interactions with CYP3A4 inhibitors and can lead to side effects.

We believe the results of the DDI study further demonstrated the differentiated pharmacological and safety profile of brilaroxazine, with data indicating its potential to provide an advantage over other treatments for patients taking multiple drugs who are at higher risk of experiencing adverse drug interactions or even discontinuation of their medications due to those interactions.

DDI evaluation is a critical clinical pharmacology study required by the U.S. Food and Drug Administration (FDA) and other regulatory agencies globally for approving a new drug to market. We look forward to submitting these data to the FDA along with the results from our pivotal Phase 3 trials as part of our New Drug Application (NDA) for brilaroxazine in schizophrenia.

Robust Development Pipeline

We believe brilaroxazine has broad therapeutic potential beyond schizophrenia, and we continue to actively explore non-dilutive financing opportunities, including partnerships, to support expansion into other neuropsychiatric indications including bipolar disorder, major depressive disorder (MDD), and attention deficit hyperactive disorder (ADHD), as well as pulmonary indications including pulmonary arterial hypertension (PAH), and idiopathic pulmonary fibrosis (IPF), that also arise from underlying dysfunction in serotonin and dopamine signaling. With no cure for these pulmonary indications, even incremental improvement over current standards of care could provide relief to patients and loved ones. Collectively, including schizophrenia, these indications represent a combined market opportunity of greater than $70 billion.

Our second drug candidate, RP1208, a triple reuptake inhibitor, was issued a composition of matter patent in Canada during the fourth quarter of 2022, adding to its existing protection in key markets around the world. We have previously been granted composition of matter patents for both brilaroxazine (RP5063) and RP1208 in the US, Europe, and several other countries.

Upcoming Milestones

We are extremely pleased with the progress we have made to date and remain optimistic about our near-term and long-term prospects as we continue to focus on advancing our pipeline of novel medicines that may have a profound impact on the lives of those affected by these medical conditions.

As already discussed, we anticipate receiving data from our pivotal Phase 3 trial evaluating brilaroxazine for the treatment of schizophrenia in mid-2023. If the results of the trial are positive, we believe we will be able to submit our NDA to the FDA setting the stage for a potential commercial launch in 2025.

In addition, we are actively pursuing strategic partnership opportunities for the further development of our other pipeline programs and expect to initiate Phase 2a studies in bipolar disorder, MDD, ADHD, PAH and IPF in 2023, subject to the receipt of non-dilutive financing. We are encouraged by our successes and remain confident in our ability to deliver shareholder value. On behalf of our deeply committed team and board of directors, I want to thank you, our shareholders, for your continued trust and support in our company. I look forward to providing additional updates on our clinical trials and other business developments in the coming months.

Sincerely,
Laxminarayan Bhat, Ph.D.
Founder, President, and CEO

About Reviva

Reviva is a clinical-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, respiratory and metabolic 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, product development, clinical and regulatory timelines and expenses, market opportunity, ability to raise sufficient funding, competitive position, possible or assumed future results of operations, business strategies, potential growth 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 filings 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.

Corporate Contact:
Reviva Pharmaceuticals Holdings, Inc.
Laxminarayan Bhat, PhD
www.revivapharma.com

Investor Relations Contact:
RedChip Companies
Todd McKnight
(917)349-2175
todd@redchip.com

LifeSci Advisors, LLC
Bruce Mackle
bmackle@lifesciadvisors.com