



Reviva Pharmaceuticals Announces First Patients Dosed in Pivotal Phase 3 Study and Long-Term Safety Trial Evaluating Brilaroxazine for the Treatment of Schizophrenia

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- RECOVER is a Phase 3, randomized, double-blind study with registrational intent -

- Reviva anticipates expanding the clinical development of brilaroxazine into other neuropsychiatric indications -

CUPERTINO, Calif., Feb. 01, 2022 (GLOBE NEWSWIRE) -- Reviva Pharmaceuticals Holdings, Inc. (NASDAQ: RVPH), 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, announced today that the first patients have been dosed in a pivotal Phase 3 study and long-term safety trial to assess Reviva's new chemical entity brilaroxazine for the treatment of subjects with an acute exacerbation of schizophrenia.

"We are pleased to announce dosing of the first patients in our pivotal, global Phase 3 RECOVER trial with registrational intent. Schizophrenia is a complex disorder that affects approximately 1% of the world's population. Despite this high prevalence, current treatment challenges remain, including suboptimal efficacy, poor tolerability, and low patient adherence. We believe that the clinical data to date supports the potential of brilaroxazine to help patients suffering from schizophrenia," said Laxminarayan Bhat, Ph.D., Founder, President, and CEO of Reviva. "Following the success of our Phase 2 study in schizophrenia, we expect to expand clinical development of brilaroxazine into other neuropsychiatric indications including bipolar disorder, major depressive disorder (MDD) and attention-deficit/hyperactivity disorder (ADHD) in 2022."

[RECOVER](#) 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. Brilaroxazine will be administered at fixed doses of 15 mg or 50 mg once daily for 28 days. A 52-week open-label extension study will further evaluate the long-term safety and tolerability of brilaroxazine in patients with stable schizophrenia. Reviva initiated the first clinical site in Bentonville, Arkansas with two patients dosed at the Pillar Clinical trial site led by its principal investigator, Dr. Fayz A. Hudefi, M.D.

Fayz Hudefi, M.D. added, "It is clear there is a void of treatment options for patients battling schizophrenia, and a large unmet need exists for a long-term tolerable treatment that can effectively address schizophrenia. We are excited to be part of the pivotal clinical trial for brilaroxazine as we dose the first patients in the global Phase 3 RECOVER trial designed to build upon Reviva's positive Phase 2 study. We remain highly encouraged by the therapeutic potential of brilaroxazine and the potential it holds to help patients and their families in need of a durable solution."

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 (RP5063)

Brilaroxazine (RP5063) is a 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 improvements 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. 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 pulmonary arterial hypertension (PAH) and idiopathic pulmonary fibrosis (IPF) with mitigation of lung fibrosis and inflammation in translational animal models. Reviva believes brilaroxazine has the potential to delay disease progression in PAH and IPF. Brilaroxazine has already received Orphan Drug Designation by the U.S. FDA for the treatment of these conditions. To learn more about the clinical and preclinical data available for brilaroxazine, please visit revivapharma.com/publications.

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 RECOVER Phase 3 trial, 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.

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