Reviva Announces Full Details of Positive Phase 2 Clinical Trial Results for Acute Schizophrenia

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- *Met endpoints for safety and efficacy in 234 patients' clinical trial with Acute Schizophrenia or Schizoaffective Disorder*
- *Met primary endpoint of reduction in Positive and Negative Syndrome Scale (PANSS) total score for Schizophrenia*
- *Mitigated positive symptoms and negative symptoms*
- *Improved social functioning and cognition.*
- *No metabolic (weight gain, elevated blood sugar, increase in lipids), no endocrine (hypothyroidism, hyperprolactinemia) side effects and no increase in suicidal ideation compared to placebo.*

CUPERTINO, Calif., April 26, 2021 (GLOBE NEWSWIRE) -- Reviva Pharmaceuticals Holdings, Inc. (NASDAQ: RVPH) (along with its subsidiaries, "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, today announced the full details of its Phase 2 clinical trial for its lead drug candidate, RP5063 (brilaroxazine) for Acute Schizophrenia.

Brilaroxazine has a unique pharmacology profile against key serotonin (5-HT) and dopamine (D) receptors, which Reviva believes can modulate and stabilize the D/5-HT system. Brilaroxazine demonstrated high affinity and selectivity for key serotonin receptors ($5\text{-HT}_{1A/2A/2B/7}$), as it is pharmacologically different from other antipsychotics through its combination of potent affinity and selectivity for target receptors implicated for schizophrenia and its comorbid symptoms.

In its randomized, double-blind, placebo-controlled, multicenter Phase 2 trial to assess the safety and efficacy of brilaroxazine in 234 subjects with acute exacerbation of schizophrenia or schizoaffective disorder, brilaroxazine met its primary endpoint, which was reduction in total Positive and Negative Syndrome Scale (PANSS) at the end of the treatment from baseline versus placebo. The drug candidate also met all safety endpoints including clinical, labs, body weight, prolactin, lipids, fasting glucose, and EKG. The PANSS total score was reduced by 20 points, a statistically significant treatment difference from the placebo. Brilaroxazine also mitigated positive symptoms and negative symptoms, and improved social functioning and cognition. Importantly, the 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 clinical study in schizophrenia.

Chief Executive Officer, Laxminarayan Bhat, PhD, commented: "Schizophrenia affects about 3.5 million people in the U.S. and 20 million globally, yet we believe there are currently no therapies that adequately address the complex mix of positive symptoms, negative symptoms, mood, and cognitive impairment associated with Schizophrenia. We are very excited about our promising phase 2 clinical data and the potential for our drug candidate to address major unmet needs associated with current treatments."

Dr. Bhat also added, "In addition to the suboptimal efficacy of current antipsychotic treatments, patients also suffer from side effects and poor tolerability, which include side effects such as akathisia, weight gain/obesity, diabetes, high cholesterol, hypothyroidism and sexual dysfunction. Moreover, we estimate discontinuation/non-compliance rates at 30 to 45% in the acute phase treatment and up to 74% in the long-term treatment of stable schizophrenia patients. Our phase 2 data shows that brilaroxazine potentially can mitigate the negative side effects of current treatments and ultimately that would hopefully improve patient's compliance to the treatment. We have published several research papers on the results of brilaroxazine's pharmacology, and the clinical phase 1 and phase 2 studies in peer reviewed journals (https://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 has 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 R1208 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 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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