Reviva Pharmaceuticals Holdings, Inc. Receives FDA May Proceed Letter for Pivotal Phase 3 Clinical Trial and Long-Term Safety Trial Evaluating Brilaroxazine For The Treatment of Schizophrenia

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- Brilaroxazine is a novel serotonin and dopamine receptor modulator currently being developed for diseases with dysfunctional serotonin signaling including neuropsychiatric and pulmonary indications -

- Initiation of both Phase 3 trials is expected by end of January 2022 -

CUPERTINO, Calif., Jan. 10, 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 the U.S. Food and Drug Administration (FDA) has notified the Company that it may proceed with Phase 3 clinical investigation of its lead candidate, brilaroxazine, a novel serotonin and dopamine receptor modulator for the treatment of schizophrenia.

"We believe that FDA clearance to proceed with initiation of a pivotal Phase 3 trial, as well as an additional Phase 3 trial focused on long-term safety, represents a transformative milestone that may support the filing and approval of a new drug application for our lead candidate brilaroxazine in patients with schizophrenia. Both Phase 3 trials will be initiated simultaneously, with the long-term safety study designed to supplement efficacy and safety data from the pivotal trial," said Laxminarayan Bhat, Ph.D., Founder, President, and CEO of Reviva. "Collectively these two trials may provide a robust Phase 3 assessment of brilaroxazine in patients with schizophrenia that we believe will complement our successful Phase 2 study. We remain highly encouraged by the therapeutic potential of brilaroxazine and look forward to initiating both Phase 3 trials by the end of January 2022."

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. 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. A full battery of regulatory compliant toxicology and safety pharmacology studies has been completed for brilaroxazine. 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. 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. Additionally, the Company 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 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:
LifeSci Advisors, LLC
Bruce Mackle
bmackle@lifesciadvisors.com

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