



Reviva Pharmaceuticals Announces Successful Completion of Pre-IND Meeting With FDA on RP5063 for the Treatment of Pulmonary Arterial Hypertension (PAH)

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SUNNYVALE, Calif.--(BUSINESS WIRE)--Reviva Pharmaceuticals, Inc. (Reviva), a privately held, clinical stage pharmaceutical company developing innovative next generation therapeutics for the treatment of CNS, cardiopulmonary and metabolic diseases, today announced that it has successfully completed a pre-Investigational New Drug Application (pre-IND) meeting with the U.S. Food and Drug Administration (FDA) for its lead compound RP5063, which is being developed for the treatment of pulmonary arterial hypertension (PAH). The FDA granted Orphan Designation to RP5063 for treating PAH in November 2016.

A pre-IND meeting provides an opportunity for open communication between a sponsor and the FDA to discuss planned IND content and to obtain guidance for clinical development. The FDA has accepted RP5063 preclinical pharmacology, safety and toxicology, and the clinical phase 1 study safety data for initiating a phase 2 study in PAH. The FDA addressed Reviva's questions and provided guidance on the RP5063 clinical development plan including potential label claim for *Disease Modification* in PAH.

"We are very pleased with the outcome of the pre-IND meeting with FDA," said Laxminarayan Bhat, PhD, Reviva's Founder, President and Chief Executive Officer. "We look forward to advancing RP5063 into a phase 2 clinical trial for PAH in early 2018."

About Pulmonary Arterial Hypertension

PAH is a progressive, life-threatening disease characterized by elevated blood pressure in the pulmonary arteries, due to severe constriction of the blood vessels in the lungs, making it more difficult for the heart to pump blood throughout the lungs for oxygenation. Based on data from the Registry to Evaluate Early And Long-term PAH disease management (REVEAL), there is an estimated five-year survival rate of 57% from diagnosis for patients in the United States. At present there is no cure for PAH, and the current treatments only reduce symptoms while some may also delay disease progression. PAH has a multifactorial pathobiology including vasoconstriction, the remodeling of the pulmonary vessel wall, and thrombosis, which all contribute to increased pulmonary vascular resistance that leads to the characteristic symptoms of PAH. According to recent reports, over 35% of the pulmonary hypertension patients also suffer from mental disorders, with the most common being major depressive disorders and panic disorders. Moreover, the prevalence of mental disorders in patients with pulmonary hypertension increases significantly with functional impairment.

About RP5063

RP5063 is a new chemical entity (NCE) with a novel, multimodal modulation of dopamine and serotonin receptors. The neurotransmitter, serotonin (5-HT), plays a critical role in the correct functioning of the human brain, lungs, and heart. Serotonin signaling is reported to be involved in pathogenesis of PAH and serotonin 5-HT_{2A/2B} receptors expressed in the lungs are recognized as novel targets for therapies for the treatment of PAH. RP5063, is a potent antagonist at the 5-HT_{2B} receptor and partial agonist at the 5-HT_{2A} receptor, and has shown robust efficacy for PAH in both inflammatory and hypoxia animal models. RP5063 lowered mean pulmonary arterial pressure, decreased respiratory resistance and brought the blood oxygen level to normal as well as significantly reducing cytokine levels (TNF α , IL1 β , IL6 and LTB4) in PAH animal models. Histopathology of the animals on these studies demonstrated that RP5063 significantly reduced pulmonary arterial vessel wall thickness and muscular tissue (<http://revivapharma.com/publications/>).

Reviva has successfully completed a multicenter, multinational phase 2 clinical study for RP5063 in patients with schizophrenia and schizoaffective disorders. RP5063 demonstrated robust efficacy with remission in acute schizophrenia and promising efficacy for comorbid negative, cognition, depression and mood symptoms. Moreover, RP5063 showed an excellent safety and tolerability profile when compared to placebo with no weight gain, metabolic, cardiac or movement side effects, which resulted in good acceptance and compliance.

Based on the available preclinical and clinical data, RP5063 has the potential to become a first-in-class therapy for the treatment of PAH and its prevailing comorbid psychiatric symptoms.

About Reviva Pharmaceuticals

Reviva Pharmaceuticals, Inc., a privately held, clinical stage pharmaceutical company, is developing a portfolio of internally discovered therapies that address unmet medical needs in the areas of central nervous system (CNS), cardiopulmonary, and metabolic diseases. Reviva has a strong patent portfolio and multiple programs in the pipeline at various stages of development. Reviva's lead product candidate, RP5063, a highly-differentiated product, is to enter pivotal phase 3 clinical trials for schizophrenia (acute and maintenance). RP5063, a potent, multimodal modulator of dopamine and serotonin receptors, offers the potential to treat other neuropsychiatric disorders with significant unmet needs (e.g., bipolar, major depression [MDD], ADHD, behavioral, and psychological symptoms in Alzheimer's and Parkinson's patients).

Reviva's leadership team has a strong background and a track record in successful product development, regulatory approval, and commercialization. Reviva was founded in 2006 and is financed by hedge funds, family offices and high-net-worth individuals. For additional information, please visit our website at www.revivapharma.com.

Forward Looking Statements

This press release contains forward-looking statements made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect management's current knowledge, assumptions, judgement and expectations regarding future performance or events, they give no assurance that such expectations will prove to be correct. Forward-looking statements are subject to a number of risks and uncertainties, but not limited to, our liability to obtain additional capital on acceptable terms, or at all, including additional capital which will be necessary to complete the clinical trials, the availability of top-line-data-delays in enrollment, delays caused by institutional review boards or regulatory agencies, shortage of clinical trial supplies, dependence on clinical trial collaborators, loss of any executive officers or key personnel or consultants. Undue reliance should be placed on forward-looking statements, which speak only as of the date they are made, and the facts and assumptions underlying the forward-looking statements may change. Except as required by law, Reviva disclaims any obligation to update these forward-looking statements to reflect future information, events or circumstances.

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