Reviva Pharmaceuticals Receives FDA Orphan Designation for Pulmonary Arterial Hypertension (PAH)

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SANTA CLARA, Calif.--(BUSINESS WIRE)--Reviva Pharmaceuticals, Inc. (Reviva), a privately held, clinical stage pharmaceutical company, today announced the granting of Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for its lead development product, RP5063, for the treatment of pulmonary arterial hypertension (PAH).

"We are pleased to receive Orphan Drug Designation for RP5063, which emphasizes the significant need for new mediations for patients suffering from PAH," said Laxminarayan Bhat, PhD, Reviva's Founder, President and Chief Executive Officer. "In conjunction with our other clinical-stage programs, this compound further enhances Reviva's value drivers."

"Based on the mechanism of action, demonstrated preclinical efficacy, and convenient delivery options for enhanced compliance, we believe that RP5063 could become a 'first in class' therapy for PAH," said Marc Cantillon, MD, Reviva's Chief Medical Officer. "Having already completed clinical studies phase 1, and phase 2 in patients with schizophrenia and schizoaffective disorders, we look forward to rapidly advancing this drug candidate into a phase 2 study in PAH patients. Many PAH patients also suffer from comorbid depression and psychosis which current medications do not address."

The FDA's Orphan Drug Designation program provides orphan status to drugs and biologics that are being developed to address rare diseases or disorders that affect fewer than 200,000 people in the U.S. With orphan designation, Reviva qualifies for various incentives including FDA assistance in clinical trial design, tax credits for clinical trial costs, an exemption from the FDA user fee, and seven years of market exclusivity in the United States, if market approval is granted for RP5063.

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 whilst some may also delay disease progression. PAH has a multifactorial pathobiology. Vasoconstriction, remodeling of the pulmonary vessel wall, and thrombosis 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 disorder. 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 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 (TNFα, IL1β, 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.

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 could be a first in class therapy for the treatment PAH and its prevailing comorbid psychiatric symptoms.

About Reviva Pharmaceuticals

Reviva Pharmaceuticals Inc. (Reviva), is located in Santa Clara, California and is a clinical stage pharmaceutical company focused on developing a portfolio of internally discovered next generation therapies that address unmet medical needs in the therapeutic areas of the central nervous system (CNS), cardiovascular and metabolic diseases. Reviva has a strong patent portfolio and several products in the pipeline at various stages of development.

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 angel investors, family offices and hedge funds. 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, judgment 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.

Contacts

Reviva Pharmaceuticals, Inc.
Laxminarayan Bhat, PhD | President and CEO
3900 Freedom Circle, Suite 101, Santa Clara, CA 95014

Phone: +1-408-816-1454 | Fax: +1-408-904.6270
E-mail: busdev.rp@revivapharma.com